

ORIGINAL

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES *ex rel.* STEVEN
WOODWARD, STATE OF ILLINOIS *ex*
rel. STEVEN WOODWARD; STATE OF
ARKANSAS *ex rel.* STEVEN
WOODWARD; STATE OF
CALIFORNIA *ex rel.* STEVEN
WOODWARD; STATE OF DELAWARE
ex rel. STEVEN WOODWARD; STATE
OF FLORIDA *ex rel.* STEVEN
WOODWARD; STATE OF HAWAII *ex*
rel. STEVEN WOODWARD; STATE OF
INDIANA *ex rel.* STEVEN
WOODWARD; STATE OF LOUISIANA
ex rel. STEVEN WOODWARD; STATE
OF MASSACHUSETTS *ex rel.* STEVEN
WOODWARD; STATE OF MONTANA
ex rel. STEVEN WOODWARD; STATE
OF MICHIGAN *ex rel.* STEVEN
WOODWARD; STATE OF NEVADA *ex*
rel. STEVEN WOODWARD; STATE OF
NEW HAMPSHIRE *ex rel.* STEVEN
WOODWARD; STATE OF NEW
MEXICO *ex rel.* STEVEN
WOODWARD; STATE OF TENNESSEE
ex rel. STEVEN WOODWARD; STATE
OF TEXAS *ex rel.* STEVEN
WOODWARD; COMMONWEALTH OF
VIRGINIA *ex rel.* STEVEN
WOODWARD; and DISTRICT OF
COLUMBIA *ex rel.* STEVEN
WOODWARD

Plaintiffs,

v.

DR. GEORGE B. JERUSALEM,
TESSE JERUSALEM, BAY
PSYCHIATRIC SERVICES, and ELI
LILLY,

Defendant.

CIVIL ACTION NO.

06-5526

UNDER SEAL

FILED

DEC 19 2006

MICHAEL F. KUNZ, Clerk
By ms Dep. Clerk

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COMPLAINT

This *qui tam* lawsuit arises principally from a national pharmaceutical kickback scheme designed to encourage the off label marketing of atypical antipsychotics. Pharmaceutical companies (including Defendant Eli Lilly) offered and paid kickbacks to physicians (including Defendant George B. Jerusalem, MD) to influence the judgment of physicians in making prescribing decisions. As a result of this illegal scheme, physicians prescribed atypical antipsychotics, in this case Zyprexa,, not based upon on what was best for the patient, but rather on which drug was made most profitable for the physicians by the drug companies. The conduct of the pharmaceutical companies and the physicians violates both the False Claims Act and the Anti-Kickback Act and more importantly endangers the health of our country's nursing home population.

The United States of America *ex rel.* Steven Woodward and the States of Illinois, California, Delaware, Florida, Hawaii, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Mexico, Tennessee, Texas, Virginia and the District of Columbia *ex rel.* Steven Woodward (collectively "Plaintiff States"), and Steven Woodward individually ("Plaintiff-Relator" or "Plaintiff-Relator Woodward"), allege as follows in support of their *qui tam* Complaint against Defendants Dr. George Jerusalem, Mrs. Tesse Jerusalem and his alter ego shell corporation, Bay Psychiatric Services, Inc. (collectively the "Bay Psychiatric Defendants") and Eli Lilly ("Lilly"):

I. NATURE OF ACTION

1. The United States and the Plaintiff States (collectively "Plaintiff Governments") allege violations of the federal False Claims Act, 31 U.S.C. §3729 *et seq.* and the analogous laws of the Plaintiff States, arising from, *inter alia*, Lilly's national, illegal off label marketing for Zyprexa, Lilly's potent atypical antipsychotic,

accomplished through a coordinated campaign of kickbacks and illegal off label promotion. An egregious example of the dangers inherent in Lilly's illegal promotional campaign is Lilly's arrangement with Dr. Jerusalem and the Bay Psychiatric Defendants. That illegal arrangement led to thousands of potent, dangerous off label drugs being prescribed to vulnerable, elderly long term care nursing home residents under Dr. Jerusalem's psychiatric "care." Those prescriptions both endangered the health of Dr. Jerusalem's patients and defrauded government funded healthcare programs of millions of dollars.

2. Dr. Jerusalem's financially driven treatment of his patients caused him to abandon the ethical canons of the medical profession as well as to neglect the appropriate standard of care to which he is bound in performing medical services. Dr. Jerusalem neglected his patients by, *inter alia*, using Zyprexa and other atypical antipsychotics off label to **chemically restrain** his nursing home patients, and otherwise provide systemic substandard psychiatric care. Dr. Jerusalem's conduct violated the fundamental human rights of his elderly patients causing them mental and physical harm.

3. Defendants' fraudulent scheme caused substantial consequences for the Government Plaintiffs. As a result of Dr. Jerusalem's activities alone, the Government improperly paid approximately \$1.4 million annually for prescriptions of Zyprexa that were ineligible for reimbursement.

4. The conduct alleged herein shows a pattern of conduct designed to maximize profits at Government insurers' expense. Dr. Jerusalem also sought kickbacks in return for writing prescriptions from drug companies other than Lilly, including AstraZeneca and Janssen.

5. Lilly engaged in the kickbacks for off label prescriptions scheme with Long Term Care (“LTC”) providers throughout the country. Lilly also engaged in the kickbacks and off label promotions schemes on a national basis for various other sales divisions within Lilly. Accordingly, the damage to the Government Plaintiffs as a result of Lilly’s national scheme is hundreds of millions of dollars.

6. Dr. Jerusalem and the Bay Psychiatric Defendants are also liable under the Federal False Claims Act and the analogous laws of the Plaintiff States for the knowing submission of thousands of false claims for payment for psychiatric services that were either never performed or for which grossly bills grossly exaggerated the nature of the service actually performed.

7. The FCA and the laws of the Plaintiff States permit any person discovering a fraud perpetrated against the Government to bring an action for himself and for the Government and to share in any recovery. Plaintiff-Relator commences this *qui tam* action individually and on behalf of the Government Plaintiffs to recover treble damages and civil penalties under the Federal False Claims Act §§ 3729-3730 and the analogous laws of the Plaintiff States.

A. FACTUAL SUMMARY

8. Defendant George B. Jerusalem (“Dr. Jerusalem”) is a psychiatrist licensed to practice medicine in the State of Florida. Dr. Jerusalem is an enrolled Medicare and Medicaid provider and pursuant thereto has at all times relevant to the Complaint been authorization under federal and state regulations to provide psychiatric therapy to elderly Medicare/Medicaid beneficiaries and to submit bills to those programs seeking reimbursement for services rendered. Dr. Jerusalem is also authorized as an

enrolled Medicare/Medicaid provider to prescribe medications attendant to psychiatric therapy that is paid for in whole or in part by such publicly funded health care programs.

9. As of April 2003, Dr. Jerusalem's patient base had swelled to an enormous number - between 3,000 and 5,000 nursing home residents. These patients were placed in his care pursuant to consulting psychiatrist agreements entered into between Dr. Jerusalem and approximately 100 to 150 long term care ("LTC") skilled nursing facilities located throughout the Florida Panhandle region. The following is a partial listing of the names and locations of some of the LTC facilities where Dr. Jerusalem served as the consulting psychiatrist in or about April 2003:

Bay Center, Panama City, FL 32405; **Bay Crest Nursing Center**, Panama City, FL 32404; **Beverly Health Care**, Emerald Shores Callaway, FL 32404; **Glencove Nursing Pavilion**, Panama City, FL 32401; **Lisenby-on-Lake**, Caroline Panama City, FL 32401; **Panama City Nursing Center**, Panama City, FL 32401; **Sea Breeze Health Care**, Panama City, FL 32405; **St. Andrews Health and Rehabilitation Center**, Panama City, FL 32405; **Washington County Convalescent Center**, Chipley, FL 32428; **Courtyard at the Mill Pond**, Marianna, FL 32446; **Jackson County Convalescent Center**, Graceville, FL 32440; **Marianna Convalescent Center**, Marianna, FL 32446; **Nursing Pavilion at Chipola Retirement Center**, Marianna, FL 32446; **Delta Health Care Center**, Destin, FL 32550; **Walton County Convalescent Center**, DeFuniak Springs, FL 32433; **Bay St. Joseph Care & Rehabilitation Center**, 220 9th St, Port St. Joe, FL 32456; **Mariner Health of Bonifay**, Bonifay, FL 32425; **Azalea Trace, Inc.**, Pensacola, FL 32514; **Baptist Manor**, Pensacola, FL 32514; **Bayside Manor**, Pensacola, FL; **Century Care Center**, Century, FL 32535; **Haven of Our Lady of Peace**, Pensacola, FL 32503; **Pensacola Health Care Facility**, Pensacola, FL 32501; **Rosewood Manor**, Pensacola, FL 32501; **Specialty Center of Pensacola**, Pensacola, FL 32526; **Tandem Health Care of Pensacola**, Pensacola, FL 32505; **The Health Center of Pensacola**, Pensacola, FL 32514; **University Hills Health and Rehabilitation**, Pensacola, FL 32514; **Bay Breeze Nursing and Retirement Center**, Gulf Breeze, FL 32561; **Sandy Ridge Care Center**, Milton, FL 32570; **Santa Rosa Convalescent Center**, Milton, FL 32570; **Andalusia Health Care, Inc.**, Andalusia, AL 36420; **Andalusia Manor**, Andalusia, AL 36420; **Opp Health & Rehabilitation Opp**, AL 36467; **Capital Health Care Center**, Tallahassee, FL 32308; **Heritage Healthcare Center**, Tallahassee, FL 32308; **Mariner Health of Tallahassee**, Tallahassee, FL 32308; **Miracle Hill Nursing and Convalescent Home**,

Tallahassee, FL 32304; **Tallahassee Memorial Long Term Care**, Tallahassee, FL 32308; **Tandem Health Care of Tallahassee**, Tallahassee, FL 32308; **Vanderbilt Life Center**, Tallahassee, FL 32308; **Westminster Oaks Health Center**, Tallahassee, FL 32308; **Gadsden Nursing Home**, Quincy, FL 32351; **Riverchase Care Center**, Quincy, FL 32351.

10. Prior to 2001, because of the atypical antipsychotics' chemically induced sedative effect, also known as somnolence, Dr. Jerusalem had already been prescribing atypical antipsychotics to geriatric patients, especially those patients diagnosed with dementia and presenting with symptoms of agitation. Somnolence is a known, common *side effect* of this potent drug class, not an indicated use. Dr. Jerusalem prescribed these expensive drugs as a medically improper and unethical **chemical restraints** to make the patients more **manageable to himself and the nursing home staffs**.

11. Atypical antipsychotics – highly potent drugs laden with numerous serious and even life threatening side effects – are primarily indicated to treat schizophrenia and bipolar mania and are **not FDA-approved to treat the elderly**. To the contrary, there have never been any scientifically legitimate studies demonstrating the efficacy or safety of the use of this potent class of drugs in the elderly demographic.

12. Instead, **the product labeling for all atypical antipsychotics currently bear a black box warning- the FDA's strongest warning - alerting prescribing physicians to the risk of increased mortality and other side effects when such drugs are prescribed to elderly patients**.

13. Nevertheless, since the launch of Lilly's blockbuster atypical antipsychotic Zyprexa, Lilly has engaged in an illegal nationwide off-label marketing campaign to cause widespread use of Zyprexa in the elderly demographic.

14. Among other things, Lilly created a 280 person sales force to promote

Zyprexa exclusively for off-label uses, specifically for Long Term Care (“LTC”) facilities to maximize off label use of Zyprexa sales in elderly population. Plaintiff-Relator was one of the LTC sales persons for three years, up until May 11, 2006.

15. The purpose and function of the LTC sales force was to market Zyprexa by, *inter alia*, extolling the drug’s efficacy for a litany of non-indicated uses to control elderly patients who presented with agitation, anxiety, insomnia, or otherwise presented with symptoms that required time intensive care through sedation.

16. Lilly’s brazen marketing efforts designed to target health care professionals who prescribe drugs to the elderly constitutes off-label marketing strictly prohibited by federal law.

17. Lilly LTC sales representatives, including Plaintiff-Relator, were trained to monitor physician prescribing behaviors to identify potential sales opportunities. Dr. Jerusalem’s high volume of prescriptions to the coveted elderly demographic made him a prime target for Lilly sales representatives.

18. To curry favor with Dr. Jerusalem, in or about 2001, Lilly LTC sales representatives Robert Dunn and Don Foy (the Lilly LTC sales team in the Florida Panhandle territory who preceded Plaintiff-Relator) began entertaining Dr. Jerusalem in an attempt to obtain a commitment from Dr. Jerusalem to prescribe Zyprexa exclusively as his atypical antipsychotic of choice. Lilly’s promises of financial benefits to Dr. Jerusalem, in cash and in kind, cemented this unlawful relationship in 2001.

19. As a result of Lilly’s kickback payments, Zyprexa became Dr. Jerusalem’s atypical of choice for approximately three years – from 2001 through October 2003. During that time, Dr. Jerusalem switched all of his patients on atypical antipsychotics to

Zyprexa. The volume, frequency, and dosages of Dr. Jerusalem's Zyprexa prescriptions increased the longer his relationship with Lilly existed. At the time of Dr. Jerusalem's increasing Zyprexa prescriptions, Florida's Medicaid program's purchases of Zyprexa proportionally skyrocketed.

20. Lilly management participated, encouraged, and authorized the unlawful payment of illegal kickbacks to Dr. Jerusalem in order to continue generating sales of Zyprexa.

21. At various times both before and after his unlawful relationship with Lilly, Dr. Jerusalem had the same illegal payment relationships with AstraZeneca Pharmaceuticals, LP and Janssen LP. Both AstraZeneca and Janssen paid improper inducements to Dr. Jerusalem to persuade him to prescribe their atypical antipsychotics Seroquel and Risperdal, respectively.

22. Dr. Jerusalem cast aside medical ethics and legal obligations as a licensed physician, choosing instead to auction his power to prescribe to the highest bidding drug company in spite of the dire medical consequences of doing so. Dr. Jerusalem's conduct is tantamount to elder abuse. Dr. Jerusalem's abusive use of atypical antipsychotics as **chemical restraints** for his own convenience and financial gain violated the human rights of his geriatric patients who are too frail to protect themselves and whose safety and well-being has been entrusted to nursing home medical professionals.

23. Dr. Jerusalem hid his neglect and abuse by falsifying patient records to reflect that he had provided therapy sessions that he never performed; by falsifying patient records to reflect that the patients were lucid enough to participate in psychiatric therapy; and by falsifying patient diagnoses and patient complaints of side effects and

ailments that did not exist. Dr. Jerusalem used these falsifications either to justify initiating a course of therapy with an atypical antipsychotic or to justify instituting wholesale switches from one atypical antipsychotic to another that was then Dr. Jerusalem's drug of choice.

24. The instant matter results from Defendants' pervasive and prolific scheme to defraud the Government Plaintiffs by, *inter alia*, 1) Lilly's national off-label marketing campaign for Zyprexa targeting LTC facilities which induced the submissions of Medicaid and or Medicare Part D claims to be submitted for uses that were off-label and therefore not covered under Medicaid/Medicare payment rules; 2) Dr. Jerusalem causing false claims to be submitted for Zyprexa and other competing atypical antipsychotics by prescribing Zyprexa and other medications off-label to geriatric patients whose prescription were paid, in whole or in part, by Medicaid and Medicare Part D or other publicly-funded health care programs; 3) Lilly and Dr. Jerusalem causing the submission of false claims for Zyprexa prescribed to geriatric Medicare and Medicaid beneficiaries solely on the basis of Dr. Jerusalem's receipt of receiving illegal payments in violation of the Anti-Kickback Statute; and, 4) Dr. Jerusalem submitting false claims for psychiatric services for Medicare and Medicaid beneficiaries that were never performed, which overstated the services performed, or which failed to meet the eligibility requirements for reimbursement under Medicare.

II. PARTIES

25. Plaintiff-Relator brings this action on behalf the United States pursuant to 31 U.S.C. §3730(b)(1) and on behalf of the Government of the State of Florida and the Governments of the remaining Plaintiff States to remedy the millions of dollars Medicare

and Medicare were induced to pay as a result of false claims submitted by, and caused to be submitted by, Defendants. The Government Plaintiffs and Plaintiff-Relator Woodward will be collectively referred to as “Plaintiffs.”

26. Plaintiff-Relator Woodward is a citizen of the United States and resident of the State of Florida. He resides at 2801 Chancellorsville Drive, #428, Tallahassee, Florida 32312. Plaintiff-Relator Woodward was employed by Eli Lilly (“Lilly”) for three years beginning in April 2003 as a Long Term Care, Specialty, Pharmaceutical Representative. His job responsibilities included marketing and promoting Zyprexa and the antidepressant Cymbalta with the goal of increasing the market presence of Lilly’s drugs in the long term care context, in particular, long term care skilled nursing facilities throughout the Florida panhandle.

27. Defendant Dr. George B. Jerusalem is a citizen and resident of the State of Florida. He resides at 3227 Country Club Drive, Lynn Haven Florida, 32444. At all times relevant to the complaint, Dr. Jerusalem has been employed as consulting psychiatrist for nursing homes in the Florida panhandle region by and through his corporate alter ego, Defendant Bay Psychiatric, a fictional corporate entity run and operated out his residence. Dr. Jerusalem, and his alter ego Bay Psychiatric, is an enrolled Medicare provider authorized to bill Medicare for psychiatric therapy provided to Medicare-beneficiary patients.

28. Defendant Tesse Jerusalem resides with her husband, Dr. Jerusalem, at 3227 Country Club Drive, Lynn Haven Florida, 32444. At all times relevant to the Complaint, Defendant Tesse Jerusalem has been employed by Defendant Bay Psychiatric as its day-to-day manager, bookkeeper and billing clerk. Within the course and scope of

her employment, she submitted false and fraudulent claims to publicly funded payors such as Medicare and Medicaid.

29. Defendant Bay Psychiatric Services, Inc. (“Defendant Bay Psychiatric”) is a licensed Florida corporation. Its principal place of business is situate at the residence of Dr. Jerusalem and his wife, located at 3227 Country Club Drive, Lynn Haven Florida, 32444. Defendant Bay Psychiatric is solely owned, controlled and directed by Dr. Jerusalem, and is liable by and through the unlawful acts committed by its officers and employees for material violations of the Government Plaintiffs’ False Claims Acts. Dr. Jerusalem is the sole psychiatrist “employed” by Defendant Bay Psychiatric.

30. Defendant Eli Lilly and Company (“Defendant Lilly” or “Lilly”) is an Indiana corporation and has its principle place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. At all times relevant hereto, Lilly was engaged in the business of licensing, manufacturing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related parties including its LTC sales force, the pharmaceutical prescription drug Zyprexa throughout the United States, including in Pennsylvania.

III. FILING UNDER SEAL

31. In accordance with 31 U.S.C. § 3730(b)(2), this complaint is filed *in camera* and will remain under seal and will not be served on the Defendants until the Court so orders. A copy of the complaint and written disclosure of substantially all material evidence and information the Plaintiff possesses have been served on the United States pursuant to 31 U.S.C. § 3730(b)(2) and FED.R.CIV.P. 4(i).

IV. JURISDICTION AND VENUE

32. This Court has jurisdiction over the subject matter of this civil action,

arising under the laws of the United States, pursuant to: (i) 31 U.S.C. §3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730; (ii) 28 U.S.C. §1331, which confers federal subject matter jurisdiction; and (iii) 28 U.S.C. §1345, because the United States is a plaintiff.

33. Jurisdiction over the state law claims alleged herein is proper under 31 U.S.C. §3732(b). This Court has supplemental jurisdiction over all state law claims under 28 U.S.C. §1367.

34. This Court has jurisdiction under 31 U.S.C. §3732(a) over Defendants because they can be found in, are authorized to transact business in, and are now transacting business in this District. This Court also has jurisdiction pursuant to 31 U.S.C. §3732(a) because at least one of the Defendants transacts business in this District.

35. Venue is proper in this District under 31 U.S.C. §3732(a) and 28 U.S.C. §1391.

V. PLAINTIFF-RELATOR'S DIRECT, INDEPENDENT NONPUBLIC KNOWLEDGE OF DEFENDANTS' FRAUDULENT CONDUCT.

36. Through his business dealings with Dr. Jerusalem and otherwise through his employment by Lilly, Plaintiff gained a wealth of direct and independent knowledge of the false and fraudulent claims and the unlawful acts described in this Complaint.

37. Plaintiff-Relator: was hired by Lilly to market Zyprexa off-label; was trained by Lilly on methods to market Zyprexa off-label during sales calls with LTC physicians; trained by Lilly about evasive conversational tactics to deflect appropriate questions about Zyprexa's lack of FDA-approved indication in the elderly demographic; was given by Lilly off-label "detail aids," including articles and studies and other materials to justify Zyprexa's off-label marketing message; and was trained by Lilly to

identify and seek out LTC physicians who could be solicited to accept kickbacks in exchange for writing large volumes of Zyprexa. Moreover, Plaintiff –Relator is personally aware that the same off-label scheme employed in the LTC market, was employed by Lilly on a national basis throughout its salesforce in all its sales divisions.

38. Plaintiff-Relator’s biggest Zyprexa customer was Dr. Jerusalem. Plaintiff-Relator had regular “business” dealings with Dr. Jerusalem and his wife. Plaintiff-Relator gained personal knowledge of Lilly’s kickback payments to Dr. Jerusalem as well as Dr. Jerusalem’s extraordinarily high sales figures from Zyprexa prescriptions for his elderly patients.

39. Plaintiff-Relator has personal knowledge of Lilly’s corporate endorsement of this unlawful national off-label Zyprexa marketing scheme for the LTC market as well as other markets and also has personal knowledge of the specific Lilly corporate personnel responsible for implementing Zyprexa’s off-label marketing.

40. Accordingly, Plaintiff-Relator is an “original source” of the non-public information alleged in this Complaint within the meaning of 31 U.S.C. § 3730(e)(4)(A) and (B).

41. Plaintiff-Relator is concurrently providing to the Attorney General of the United States, the United States Attorney for the Eastern District of Pennsylvania a disclosure statement summarizing and supported by known material evidence in accordance with the provisions of 31 U.S.C. §3730(b)(2) and applicable state law.

VI. BACKGROUND

A. Plaintiff-Relator’s Employment at Lilly

42. From 1997 through 2000, Plaintiff-Relator honorably served the United States of America as a non-commissioned officer in the United States Army. In September 2000, Plaintiff-Relator was honorably discharged from military service.

43. In April 2003, Plaintiff-Relator was hired by Defendant Eli Lilly Plaintiff-Relator as a Long Term Care (“LTC”), Specialty, Pharmaceutical Representative. Lilly considered the LTC sales division to be a “specialty” sales division. Specialty Sales requires a higher order of skills and responsibilities than the average pharmaceutical sales representative.

44. Lilly’s nationwide LTC 280 person sales force were the foot soldiers deployed by Lilly to actively and aggressively promote Zyprexa to LTC facilities that care for the elderly demographic, despite the lack of any clinical trials or FDA approval for the use of Zyprexa in the elderly. As alleged in the background discussion of Lilly and its off-label promotion of Zyprexa *infra* at subsection C, Lilly trained its LTC sales force to maximize Zyprexa’s LTC care revenues.

45. Other Lilly LTC sales persons known to Plaintiff-Relator during his employment, some of who have been promoted or fired as noted, include Pam Sweeny – now Pam Evans (promoted) Kari Lee, Bobby Dunn (promoted specifically because of the Zyprexa business he developed through Dr. Jerusalem), Don Foy (promoted for the same reason as Mr. Dunn), Anneka King (fired), Jerry Bell (fired), Renee Maning (employment status uncertain), Risa Gomez (employment status uncertain).

46. Plaintiff-Relator was continuously employed as a Lilly LTC sales representative for three years until a few months ago in May 2006. Plaintiff-Relator’s job responsibilities included marketing and promoting Lilly’s atypical antipsychotic Zyprexa

for the stated purpose of increasing the market presence of these drugs in the long term care context, in particular, long term care skilled nursing facilities throughout the Florida panhandle.

47. Lilly employed a specific sales division devoted to calling upon LTC facilities because of their indigenous population of almost exclusively elderly clientele – one of Lilly’s primary target demographics for off-label growth of Zyprexa.

48. Plaintiff-Relator’s territory was the Florida Panhandle region. Lilly stationed its Long Term Care sales force “specialists” in every state. Lilly recognized that certain states were “gold mines” for the Long Term Care market segment. Lilly recognized Florida to be a “heavyweight” state due to its extraordinarily high concentration of geriatric Floridians living within the state’s borders. California and Texas were two other states (among others) to which Lilly assigned a relatively large LTC sales force. Examples of states having a minor LTC presence would include the Dakotas, Ohio, and Oregon.

49. Lilly carefully monitored the success of its LTC off-label marketing sales. The barometer of Plaintiff-Relator’s sales performance was the *total sales revenue* generated by him for Zyprexa in LTC facilities in the Florida Panhandle region. Because Lilly’s kickback arrangement with Dr. Jerusalem was already in place when Plaintiff-Relator was hired by Lilly, Plaintiff-Relator had no trouble meeting the Lilly sales goals. Plaintiff-Relator’s annual Zyprexa sales revenues in the Long Term Care demographic exceeded \$1 million.

B. Defendants

1. The Bay Psychiatric Defendants

50. Dr. Jerusalem completed medical training to be a surgeon in his native

country, the Philippines. This training did not qualify him to practice medicine in the United States. Dr. Jerusalem procured licensure to practice *psychiatry* in the United States upon completing an internship in psychiatry, in accordance with protocol, despite having received no formal education in this medical specialty in the United States or elsewhere.

51. Dr. Jerusalem has practiced “psychiatry” through his corporation Bay Psychiatric, for over 20 years. Dr. Jerusalem does not engage in the private practice of psychiatry. Rather, his practice is devoted to the treatment of Medicare and Medicaid beneficiaries who reside in LTC facilities.

52. Dr. Jerusalem’s wife, Tesse Jerusalem, at all times relevant to the Complaint managed the business affairs of Bay Psychiatric Services. This job included processing prescriptions, maintaining patient records and the preparation and submission of claims to Medicare for psychiatric services ostensibly performed by Dr. Jerusalem for his geriatric patients.

2. *Defendant Lilly and Its Illegal Off-label Marketing of Zyprexa*

53. Lilly is the manufacturer of the former number one prescribed atypical antipsychotic, Zyprexa. Zyprexa has been Lilly’s largest selling drug for a number of years. Lilly’s annual profits from Zyprexa sales have been astounding. For example, in 2002, Zyprexa generated \$3.69 billion in revenue for Lilly, making it Lilly’s top seller and the sixth-largest-selling drug in the world. In 2003, Zyprexa sales rose to \$4.4 billion and assumed the rank of world’s fifth best selling drug.

54. The FDA initially approved Zyprexa on September 27, 1996 for the treatment of adult schizophrenia. The drug subsequently received approval to treat adult bipolar mania. **Zyprexa has not been approved for the treatment of any other**

disorder; nor is the drug indicated at all for use in the elderly population.

55. Even before Zyprexa had received FDA approval, Lilly was planning a national, aggressive off-label marketing campaign for Zyprexa, as evidenced by its maintenance of an entire sales force devoted to off-label promotion of Zyprexa in the LTC population.

56. Lilly marketed Zyprexa off-label because the drug's on-label uses were far too narrow to achieve the blockbuster revenues Lilly had planned for the drug. Less than 7% of the United States' adult population is diagnosed with an indicted use of Zyprexa.

57. Two roadblocks impeded Lilly's planned saturation of the LTC market with Zyprexa. First and foremost, Zyprexa is not approved to treat the elderly for any indication. Second, few elderly patients are diagnosed with schizophrenia or bipolar disorder, the only two indications for which Zyprexa is indicated in any population.

58. Lilly designed a deceptive and misleading marketing campaign to create a LTC market for Zyprexa. Lilly falsely touted Zyprexa's superior efficacy in treating the generic mood and behavioral symptoms of schizophrenia and bi-polar disorder; symptoms that Lilly knew were also prolific in the elderly population.

59. The purpose of the deceptive scheme was to create the misimpression that geriatric patients presenting with a myriad of symptoms that did not fit into a precise diagnostic category were Zyprexa candidates, thereby creating a broad, ill-defined market for Zyprexa in the elderly demographic.

60. The generic symptoms Lilly unlawfully promoted Zyprexa to treat mimicked those of dementia and/or Alzheimer's, including agitation, anxiety, and insomnia. By marketing the drug for the treatment of *symptoms* for which Zyprexa was

not approved, Lilly violated strict FDA labeling regulations detailed *infra*.

61. Lilly encouraged use of Zyprexa in the elderly to treat any symptoms that might be categorized as relating to dementia. To assist in these efforts, Lilly instructed the sales force to use patient profile detail aids whose focus was on “behavior treatment” such as agitation, suspiciousness, depressive mood, anxiety, and lack of concentration. By focusing on symptoms rather than the diagnoses of schizophrenia or bi-polar, Lilly intended to overcome Zyprexa’s lack of any FDA approved market for Zyprexa in the LTC demographic.

62. By directing its sales force to focus on behavioral and cognitive symptoms such as anxiety, depression, agitation, Lilly was propagating the misleading message that Zyprexa was indicated for the treatment of dementia.

63. Lilly’s marketing tactics also capitalized on the inherent high stress of healthcare providers employed in nursing homes and residential care facilities. Such health care providers frequently experience considerable stress to meet the needs and demands of too many residents. Lilly LTC sales representatives were trained to cater to physicians’ frustrations with difficult, time-intensive patients by marketing Zyprexa’s efficacy in mitigating the agitation and demands of elderly patients. In truth, this was Lilly’s thinly-veiled marketing of Zyprexa as an effective **chemical restraint** for demanding, vulnerable, and needy patients.

64. Lilly organized its Zyprexa sales operations into regional divisions. The State of Florida fell within Lilly’s West division. Lilly’s LTC Director for the entire LTC West division was Mike Murray. Initially, Murray was responsible for Zyprexa sales exclusively in the LTC market; subsequently his portfolio expanded to include Zyprexa

and Cymbalta. Tom Olzinski was Lilly's LTC Eastern Division Director. Lilly's Neuroscience Director, Grady Grant, oversaw the entire LTC division.

65. Plaintiff-Relator, as a LTC sales representative working under Murray gained inside, non-public information about Murray's implementation of Lilly's illegal off-label marketing and promotional practices for Zyprexa.

66. Murray was personally involved in implementing and overseeing Lilly's illegal LTC sales practices and also possessed a wealth of first hand knowledge of Lilly's corporate endorsement of such practices. By March of 2006, however, Murray, had become disgruntled with Lilly. Accordingly, Murray met with upper corporate management to discuss a severance from Lilly. At that time, Murray threatened to disclose information about Lilly's off label marketing scheme unless he received a beneficial severance.

67. Lilly's concern about Murray's knowledge of Lilly's illegal marketing practices was a subject of discussion amongst Lilly LTC sales representatives in or about the summer of 2006. Lilly arranged for Murray to meet with Lilly's corporate products liability attorney. In July 2006, Murray was offered and accepted a generous severance package in exchange for Murray's execution of a Non-disclosure Agreement.

68. Lilly disseminated training materials and required salespersons to attend training seminars during annual National Sales Meetings (held in Atlanta, Georgia), periodic Regional sales meetings (held in South Carolina) and quarterly District sales meetings (held in Florida).

69. Among other things, Lilly LTC salespersons including Plaintiff-Relator, engaged in role playing exercises that emulated physician sales calls. Since the LTC sales

representatives could not discuss Zyprexa's indicated uses in the elderly demographic - because there were none - salespersons were taught to steer conversations with physicians to the discussion of the generic symptoms common in the elderly LTC demographic and to emphasize that Zyprexa was a superior drug to treat "hostility and aggression."

70. Lilly also created fictitious stereotypical patient profiles of agitated, hostile geriatric patients to present to potential referring physicians. Lilly trained its sales representatives to suggest that such hypothetical patients would be medically indicated for treatment with Zyprexa.

71. For example "Rose" was the detail piece used by LTC sales representatives to represent the angry and hostile elderly patient complaining of symptoms such as anxiousness, irritability, mood swings, and disturbed sleep.

72. The detail piece was large color picture of "Rose", a woman snarling at the camera. Words such as "Anger" and "Hostility" were imprinted directly on the "Rose" detail aid. Plaintiff-Relator was instructed to show this disturbing image to clients to reinforce the marketing message that Zyprexa can treat this angry, agitated, and difficult patient.

73. Another profile that Lilly trained its sales force to address was the "sundowner" - the elderly LTC facility resident who has trouble sleeping at night and who sleeps during the day. She is agitated, forgetful and easily confused, particularly at night. In other words, this version of "Rose" may be experiencing dementia or mild Alzheimer's, or any number of health concerns associated with age and declining health, but there is absolutely no indication that she is schizophrenic or bipolar. A large number

of nursing home residents fit the “sundowner” profile, but are not psychotic, schizophrenic, or bipolar.

74. Lilly also encouraged its LTC representatives to offer financial incentives to physicians to write off-label Zyprexa prescriptions. The payment of and acceptance of the financial incentives in exchange for prescriptions violated the federal Anti-Kickback Statute. One method employed by Lilly to conceal kickback payments under the guise of legitimacy was the creation of a “speaker” program. Lilly even established an annual budget for LTC sales representatives to invest in speaker fees/honoraria as well as an annual entertainment budget to impress and attract physicians’ business.

75. For example, Lilly budgeted an extravagant **\$100,000 annually** for Plaintiff-Relator to spend on speaker fees/honoraria. Not surprisingly, the bulk of this budget – approximately \$50,000 annually – went to Dr. Jerusalem. in payment for speaking engagements. Lilly also paid “in kind” kickbacks to Dr. Jerusalem in connection with these speaking engagements. Lilly paid exorbitant sums for Dr. Jerusalem’s and his wife’s incidental expenses for speaking engagements, such as travel, first-rate lodging, extravagant meals and entertainment. Plaintiff-Relator also spent the bulk of his entertainment budget on Dr. Jerusalem to maintain his extraordinary Zyprexa sales.

76. Plaintiff-Relator has personal knowledge that Lilly established similar illegal referral relationships with health care providers throughout the United States.

77. By and through Lilly’s off-label marketing, Lilly harmed the Government Plaintiffs and jeopardized the health and safety of the tens of thousands of fragile elderly Medicaid beneficiaries across the country.

VII. THE PUBLICLY-FUNDED HEALTH BENEFITS PROGRAMS

A. The Medicaid Program

78. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded by Medicaid, at least prior to the implementation of the Medicare Part D program on January 1, 2006, was funding for the prescription drug needs of its beneficiaries.

79. At all times relevant to the Complaint, in Florida, and most other states, Medicaid was an open-ended federal-state matching program. The federal government contributes a fixed percentage of the state's Medicaid costs each year; however, the exact percentage the federal government contributes varies year to year using a formula that takes into account the state's per capita income relative to the national per capita income.

80. In 2003, the federal government funded 62% of Florida's Medicaid costs. The percentage of federal contribution hovered on or about that percentage at all times relevant to the complaint.

81. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is limited to "covered outpatient drugs." 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2),

(3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.* at §1396r-8M(3).

82. A medically accepted indication, in turn, is a use which is listed in the labeling approved by the FDA, or use of which is supported by one of the drug 'compendia identified in the Medicaid statute. *Id.* §1396r-8(k)(6). During the time period relevant to this Complaint, the off-label uses of Zyprexa promoted by Zyprexa were not eligible for reimbursement from Medicaid because such off-label uses were neither listed in the labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid statute. Use of Zyprexa, for example, for dementia, or for anxiety or depression in the elderly is not supported by the compendia as medically safe and effective, although Lilly has promoted the drugs for those and other unauthorized uses in the ways set forth below.

83. There is a predominant usage of atypical antipsychotic by beneficiaries of the Medicaid program due to the high incidence of mental illness in the demographic eligible to enroll as Medicaid beneficiaries. Lilly's Zyprexa was the most commonly prescribed atypical antipsychotic at all times relevant to the complaint.

84. At all time relevant hereto, the LTC pharmacies that arranged for the pharmaceutical needs of Dr. Jerusalem's patients were pharmacy benefit providers enrolled in the Medicaid program. These LTC pharmacies included PharmMerica, Neighbor Care, and OmniCare. Defendants used the LTC Pharmacies as the instrument of their fraud as it was the pharmacies that unwittingly submitted the false Zyprexa claims.

B. The Medicare Program

85. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to beneficiaries of the Medicare insurance program is paid in whole or in part by the United States.

86. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of needy classes of individual healthcare patients pursuant to federal regulation.

87. At all times relevant hereto, the Dr. Jerusalem, by and through Bay Psychiatric, was a participating provider in Medicare.

VIII. PSYCHIATRIC CARE OF THE ELDERLY IN THE LONG TERM CARE SETTING.

A. LTC Pharmacies Arrange for and Bill the Government Plaintiffs' for the Drugs Prescribed by Dr. Jerusalem to LTC Facility Residents.

88. LTC skilled nursing facilities are places where nurses and medical professionals serve elderly, extremely frail residents who need continuous care with their basic activities of daily living. Among the continuous care LTC facilities provide to elderly patients is psychiatric care. The pharmaceutical needs of LTC nursing home residents are arranged for and provided by LTC pharmacies.

89. LTC pharmacies are known as 'closed-door' pharmacies. Closed-door pharmacies are full-service pharmacies, but they do not provide services to the general public; rather, they exclusively fill the prescription medication needs of LTC patients.

90. LTC pharmacies, including those servicing the LTC facilities at which Dr.

Jerusalem served as the psychiatric consultant, regularly bill Government-funded healthcare plans such as Medicaid for medications prescribed by medical professionals working onsite at the nursing homes.

91. Dr. Jerusalem devoted his entire practice of psychiatry to the treatment of geriatric residents of LTC nursing homes. Dr. Jerusalem, a veteran of the LTC health care field, and an experienced biller of psychiatric services to Medicare for the same patients to whom he was prescribing medication, knew his patients' prescription drug costs were funded in whole or in part by publicly-funded healthcare programs, including Medicaid and Medicare.

92. When a patient in a nursing home requires a prescription medication, physicians give written or verbal prescription orders for their patients to nurses. The nurses transmit the prescription orders verbally or by facsimile to the responsible LTC pharmacy clerical data entry personnel to be entered into the LTC pharmacy's computerized order entry system.

93. Once a prescription order is entered into a LTC pharmacy's order entry system, a pharmacist fills the prescription based on the physician's request. The medication is then shipped to the nursing home facility where the patient resides. Once the prescription is filled, the LTC pharmacy prepares a claim to be submitted to the Government for reimbursement for the cost of the prescription drug. The vast majority of elderly LTC residents rely upon Medicare and Medicaid to pay for their health benefits.

B. Lilly's LTC Sales Force Implements Lilly's Illicit Off-Label Marketing and Sales Scheme.

94. One of Lilly's primary strategies for marketing Zyprexa was to target pharmacies that service LTC skilled nursing facilities.

95. Plaintiff-Relator has personal knowledge that Lilly aggressively promoted Zyprexa off-label throughout the country through its 280 person long-term care sales force dispersed nationwide. In addition to communicating such practices during frequent regional and district Lilly sales conferences, Lilly engrained its off-label marketing message during once or twice annual national sales meetings. During national sales meetings, specific gatherings, seminars, and training sessions were held solely for the Lilly LTC sales representatives.

96. The following is a summary of tools, methods, and means used by Lilly to execute its off-label marketing scheme that are pleaded with specificity in this Complaint:

- a. Use of LTC sales representatives to call upon LTC facilities, LTC pharmacies, and LTC prescribing physicians to promote a myriad of dangerous off-label uses of Zyprexa for the purpose of inducing Zyprexa to be prescribed to geriatric LTC patients off-label;
- b. LTC sales representatives' unsolicited use of non-scientific literature ostensibly "supporting" Zyprexa as safe and effective for the off-label uses being promoted by Lilly's LTC sales representatives;
- c. LTC sales representatives' use of scientific literature and deceptive detail aids describing off-label uses of Zyprexa tailored to the LTC setting;
- d. Making payments to physicians disguised as fees for "speaking programs" for the sole purpose of inducing physicians to write prescriptions for off-label prescriptions of Zyprexa in the elderly population;
- e. Giving lavish gifts to physicians in the form of chartered fishing trips for physicians and their friends, expensive dinners and entertaining, among other things, for the sole purpose of inducing physicians to write prescriptions for off-label prescriptions of Zyprexa in the elderly population;
- f. LTC sales representatives use of confidential private health information to identify LTC physicians in their

territories with large volume practices whose use of Zyprexa could be increased as targets for cold call visits to promote Zyprexa off-label;

- g. Monitoring LTC sales representatives ability to obtain confidential private health information; and,
- h. Monitoring the success of the off-label promotional program and their off-label LTC sales force by carefully monitoring sales revenues of each sales representative and setting high sales goals expected to be met as an ostensible measure of job performance.

97. Lilly's illegal and zealous off-label over promotion of Zyprexa off-label was a calculated campaign to increase sales of Zyprexa in the elderly population for dementia symptoms, agitation, insomnia and many other generic symptoms without regard for the safety of the patients for these untested, unapproved uses.

98. Lilly succeeded. Lilly's LTC sales force was the most successful of all Lilly's sales teams based upon earnings per salesperson. Specifically, Plaintiff-Relator gained personal knowledge from Lilly corporate employees during Lilly's regional and national sales conferences, and from the sales data Lilly made available to him, that the revenues generated per LTC sales representatives far exceeded the revenues generated per sales representative in any other sales division.

99. To sustain this success, Lilly bestowed LTC sales representatives with large budgets to expend upon physicians to maintain Zyprexa's off-label market dominance and extraordinary revenues in the geriatric market.

100. Lilly LTC sales representatives' actual customers were the 'closed-door' pharmacies that filled the prescriptions. For Plaintiff-Relator, these LTC pharmacies included PharmMerica, Neighbor Care, OmniCare and APS. However, Lilly LTC salespersons were evaluated on total Zyprexa sales revenues. Physicians, not the LTC

pharmacies, had the greatest impact on sales since the physicians wrote the prescriptions.

101. Lilly LTC representatives were therefore financially incentivized to devote the most time marketing and promoting Zyprexa in LTC skilled nursing facilities, particularly to the staff LTC physicians who prescribed medications for the LTC residents.

102. Lilly LTC sales representatives' relationships with LTC pharmacies were nonetheless important to maximizing revenues from the marketing and promotion of Zyprexa. To target the most influential doctors, Lilly encouraged LTC representatives to develop personal relationships with the LTC pharmacies to gain access to the pharmacies' local prescribing data. Plaintiff-Relator sometimes obtained this information verbally, and other times the data was provided in hard copy in the form of printed reports.

103. Plaintiff-Relator and the other specialty sales force were also directed by Lilly to obtain Drug Utilization reports, also known by the acronym "DURs," from the skilled nursing home executive staff. These reports were obtained by sales representatives' leveraging their personal relationships with the Director of Nursing at each individual nursing home.

104. A "Drug Utilization Report" is a report delineating protected health information detailing which patients were taking which drugs and which physician was prescribing those drugs. Software provided by Lilly loaded on Plaintiff-Relator's Lilly-owned laptop computer enabled Plaintiff-Relator to cull the larger report down to focus on patients prescribed antipsychotics and the names of the doctors 'writing' those prescriptions.

105. Lilly enforced this directive by meticulously tracking whether or not Lilly sales representatives succeeded in obtaining these reports. Plaintiff-Relator was required as part of his job responsibilities to report when he obtained DURs containing protected private

medical information. Lilly tracked whether or not he achieved that goal. During one sales quarter, Lilly set a “goal” for Plaintiff-Relator to procure six up-to-date DURs.

106. An integral part of Lilly’s unlawful marketing tactics implemented through its LTC sales force involved, *inter alia*, paying physicians to prescribe Zyprexa for symptoms and illnesses that were unrelated to schizophrenia and bi-polar to the physically frail elderly population. Lilly LTC sales representatives used their improper access to DURs to identify physicians to solicit to enter into unlawful financial relationships.

107. The fierce competition among the atypical antipsychotics for market share and the astronomical revenues attendant to market share drove this unlawful conduct. For example, the following charts set forth the total US Sales dollars in thousands for 1999-2004 and the total number of prescriptions dispensed for the competing antipsychotics for 1999-2004 for the entire class of atypical antipsychotics:

Antipsychotics - Total U.S. Sales \$ in Thousands (000)

Rank	Drug	2004	2003	2002	2001	2000	1999
Class Total		\$9,053,841	\$8,053,072	\$6,619,177	\$5,374,591	\$4,035,986	\$3,162,914
1	Zyprexa	\$2,825,896	\$3,156,664	\$2,972,044	\$2,514,809	\$1,941,785	\$1,519,390
2	Risperdal	\$2,072,622	\$2,024,418	\$1,854,064	\$1,622,861	\$1,325,278	\$1,045,533
3	Seroquel	\$1,978,618	\$1,507,098	\$1,090,417	\$703,666	\$423,493	\$223,653
4	Abilify	\$1,008,620	\$488,122	\$22,072	-----	-----	-----
5	Geodon	\$498,977	\$358,265	\$253,124	\$141,285	-----	-----

*Source: IMS Health, IMS National Sales PerspectivesTM, 1/2005

Antipsychotics - Total U.S. Dispensed Scripts in Thousands (000)

Rank	Drug	2004	2003	2002	2001	2000	1999
Class Total		42,269	38,825	34,705	29,882	25,204	19,806
1	Risperdal	11,486	11,376	11,400	10,547	9,214	6,662
2	Seroquel	10,624	8,186	6,108	4,184	2,649	1,386
3	Zyprexa	9,303	10,596	10,302	8,694	7,068	5,382
4	Abilify	2,956	1,437	21	*****	*****	*****
5	Geodon	1,839	1,424	1,077	491	*****	*****

See http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_18731_63237611,00.html, dated July 17, 2006. (citing **Source: IMS Health, IMS National prescription Audit Plus™, 1/2005)

108. As a result of, *inter alia*, the unlawful inducements Lilly regularly paid in cash and in kind to physicians and Lilly's unlawful and misleading Zyprexa off-label promotional sales tactics, research now shows that nursing home residents are being fed antipsychotics in record numbers. A study published in the June 13, 2005 Archives of Internal Medicine examined the quality of antipsychotic prescriptions in about 2.5 million Medicaid patients in nursing homes and found that "over half (58.2%)," received antipsychotics that exceeded the maximum recommended dosage, received duplicate therapy, or under the guidelines, more than 200,000 nursing home residents received antipsychotic therapy but had "no appropriate indications for use."

IX. DEFENDANTS' KICKBACK SCHEME TO DEFRAUD THE GOVERNMENT PLAINTIFFS.

A. The Bay Psychiatric Defendants and Lilly Enter into An Illegal Agreement Under Which Lilly Paid Dr. Jerusalem Lucrative Kickbacks to make Zyprexa his Atypical of Choice.

1. Dr. Jerusalem's Vast LTC Patient Base.

109. LTC nursing facilities do not maintain a psychiatrist on-staff. Rather, nursing homes commonly use the psychiatric consultation-liaison model to arrange for psychiatric care for residents. The psychiatrist consultant is supposed to help with diagnosis, optimization of medication use, and simplification of medication regimens. A psychiatrist appointed as a consultant to a nursing home is often asked to assess disruptive patients.

110. Dr. Jerusalem created a lucrative “niche” market in the Florida Panhandle as a contracted, consulting psychiatrist for approximately 150 LTC skilled nursing facilities. A partial listing of the nursing homes for which Dr. Jerusalem was the consulting psychiatrist is attached hereto as Exhibit “A.”

111. Plaintiff-Relator was in attendance at several of Dr. Jerusalem’s consulting psychiatrist agreement “signings.” Plaintiff-Relator brought pizza on behalf of Lilly as a congratulatory gesture.

112. The Florida Panhandle is the large region of the state of Florida encompassing the westernmost 16 counties in the state. It is a narrow strip lying between Alabama and Georgia to the north and the Gulf of Mexico to the south. Cities in the Panhandle include Tallahassee, Pensacola, and Panama City.

113. Dr. Jerusalem orchestrates 95% of the psychiatric referrals for skilled nursing facilities in the Florida Panhandle area – he has quite literally monopolized the LTC psychiatric market in this region of Florida. As Lilly’s Florida panhandle sales representative, Dr. Jerusalem *was* Plaintiff-Relator’s market.

114. Dr. Jerusalem frequently boasted about the plethora of patients entrusted to his psychiatric care. During Plaintiff-Relator’s employment with Lilly on or about April 2003, Dr. Jerusalem represented himself to be the sole and exclusive source of psychiatric

care of between 3000 and 5000 patients.

115. Dr. Jerusalem's monopoly unfortunately came at the expense of patient welfare and safety. Dr. Jerusalem's patient base is so large and spread out in so many facilities throughout the vast Florida panhandle area that it is practically impossible for one man to provide the necessary, time-intensive mental health services at an appropriate standard of care to each of his patients.

116. Plaintiff-Relator was often a sounding board for the LTC staff's frequent complaints about Dr. Jerusalem's failure to evaluate and monitor patients - most of whom he did not bother to see personally. Rather, he devoted barely enough time at any facilities to do much more than write prescriptions for which he received kickbacks.

2. Dr. Jerusalem's Abuse of Atypicals as a Chemical Restraint.

117. Zyprexa, the potent drug promoted and marketed by Plaintiff-Relator on behalf of Lilly, belongs to a class of drugs known as "second-generation antipsychotics" or "atypical antipsychotics." This class of drugs is FDA-approved to treat specific, narrowly defined symptoms of Schizophrenia and Bipolar Disorder, which are rare and devastating mental illnesses diagnosed in an extremely small percentage of the United States population. Persons diagnosed with severe mental illnesses tend not to be residents of LTC skilled nursing facilities. Dr. Jerusalem had few, if any, patients diagnosed with either of these mental illnesses.

118. Atypical antipsychotics are powerful medications, laden with serious treatment-emergent side effects. Zyprexa and the other atypical antipsychotics have not received FDA-approval to treat the elderly because of atypicals' serious risk of harm and the lack of scientific evidence of its safety and efficacy in this population. Accordingly, each

and every Zyprexa prescription Dr. Jerusalem wrote to his elderly patients were off-label because the drug was prescribed to the elderly and those elderly patients were neither schizophrenic nor demonstrated the manic symptoms or mixed symptoms of bipolar disorder.

119. Why would Dr. Jerusalem prescribe a potent drug meant to treat schizophrenia and bi-polar disorder diagnosed in patients ages 18-64 to physiologically frail nursing home residents who did not suffer from these relatively rare serious mental illnesses, when the drug was not even approved for the treatment of the elderly?

120. Among the most common, treatment-emergent adverse side effects of Zyprexa and the other atypical antipsychotics is somnolence. Somnolence is defined as sleepiness, the state of feeling drowsy, ready to fall asleep.

121. Dr. Jerusalem *knowingly* medicated his patients with incapacitating antipsychotic agents such as Zyprexa to control the behavior of his patients that he did not have time to treat personally, especially the those patients who required burdensome, time intensive care, as well as those patients who demonstrated “oppositional” and “defiant” behavior.

122. Dr. Jerusalem’s unethical and unlawful use of medication, off-label, as a **chemical restraint** was designed to put his patients in a zombie-like state, unable to complain or object. This twilight-like state was known in the LTC business as the patient being “*snowed*.”

123. The use of atypical and typical antipsychotic drugs to control the behavior of elderly nursing home residents who are not psychotic constitutes an **unlawful chemical restraint**.

124. Government healthcare programs would not have paid claims for this

improper use of Zyprexa had it known the truth.

125. As the only major Zyprexa prescriber in the panhandle area of Florida, Dr. Jerusalem was the epicenter of business for Plaintiff-Relator, as well as for every competitor of Plaintiff-Relator. Plaintiff-Relator's sales figures soared because of Dr. Jerusalem's prescriptions. Dr. Jerusalem and Tessa Jerusalem abused the knowledge that Plaintiff-Relator's Zyprexa sales hinged on the volume of Dr. Jerusalem's prescriptions for Zyprexa.

126. One particularly large sales quarter for Plaintiff-Relator, Tessa Jerusalem excitedly asked Plaintiff-Relator during one of their regular business lunches whether he had received his sales numbers and overtly suggested that Plaintiff-Relator's sales figures had increased dramatically due to Dr. Jerusalem's increased off-label use and his use of higher doses of Zyprexa.

127. Among the various ways Dr. Jerusalem contrived higher sales for Plaintiff-Relator was to increase the dose of his patients' Zyprexa prescriptions, with a resulting increase in Plaintiff-Relator's sales figures. Another method was to prescribe lower doses at more frequent intervals, instead of prescribing a single-higher dose pill that would have been more cost effective.

128. Dr. Jerusalem used his huge market as a bargaining chip to solicit payments from Lilly and other manufacturers. Dr. Jerusalem made it clear to Plaintiff-Relator that his atypical of choice was always up for sale and that to remain loyal to the Lilly brand, he expected preferential financial treatment from Lilly.

129. Dr. Jerusalem made numerous thinly-veiled threats that he would take his business elsewhere if his needs were not met. Because he had so many patients, Dr. Jerusalem alone generated approximately a million dollars annually in Zyprexa sales.

B. Dr. Jerusalem Actively Solicits Kickbacks

130. Dr. Jerusalem's monopoly on the LTC market in the Florida panhandle empowered him to demand lucrative kickbacks, in the form of cash, expensive dinners, and other entertainment, in exchange for his willingness to prescribe the winning bidder's medication to his stable of 3000 to 5000 patients.

131. When Plaintiff-Relator commenced his employment with Lilly in April 2003, Dr. Jerusalem was already a Lilly supporter. Plaintiff-Relator's Lilly LTC sales predecessors were Robert Dunn and Don Foy. They were both promoted as a result of their dealings with Dr. Jerusalem. Dunn and Foy explained to Plaintiff-Relator how Lilly had won Dr. Jerusalem's business in exchange for chartering fishing trips for him and his friends in 2001.

132. Plaintiff-Relator also learned that Dr. Jerusalem had received preferential financial treatment from Janssen Pharmaceuticals and had widely prescribed Janssen's antipsychotic Risperdal before Dunn and Foy had persuaded Jerusalem to switch his patients to Zyprexa. Once Lilly won him over with more enticing kickbacks than Janssen was apparently offering, Dr. Jerusalem made a wholesale switch to Zyprexa.

133. Dr. Jerusalem's demands for kickbacks were unrelenting. He requested and received extravagant dinners costing between \$75 and \$125 per person and also was paid the top rate of \$1500 to speak on behalf of Zyprexa on a regular basis. He also had all of his travel expenses incident to those engagements paid for, and received an endless supply of other gifts including bottles of wine, cards, and cakes for birthdays, and so on.

134. During the time of Lilly's preferred status with Dr. Jerusalem, Lilly had a 70% market share of the antipsychotic medications prescribed in the LTC market.

135. Dr. Jerusalem plainly stated to Plaintiff-Relator and other Lilly sales representatives that Dr. Jerusalem prescribed medications based upon who paid him the most money for speaking engagements as well as provided him with other financial remuneration. Thus Lilly and other drug companies paid him substantial sums to lecture about Zyprexa. .

136. Lilly and the other manufacturers paid honoraria or speaker fees as part of their overall off label marketing scheme. Lilly management approved huge speaker fee budgets as a means to generate large payments to physicians who were willing to prescribe Zyprexa off label. The LTC representatives were given annual speaking fee budgets as large as \$100,000 to induce physicians to write off label.

137. In Dr. Jerusalem's case the speaking fees were typically \$1500 for a lunchtime lecture.

138. Dr. Jerusalem was typically retained for three speaking engagements per month, translating into approximately \$50,000 annually.

139. To complete the payment process to, *inter alia*, Dr. Jerusalem, Plaintiff-Relator would contact the Lilly Speaker's Bureau and the Lilly Speaker's Bureau arranged for the check to be sent.

140. Lilly established an annual budget to finance the speaking engagements. The budget was theoretically capped at \$100,000 per sales representative. To get around this \$100,000 cap for "high roller" physicians like Dr. Jerusalem, the LTC representatives would arrange for a physician to be hired by other LTC sales representatives to speak in their territories.

141. Plaintiff-Relator has personal knowledge that Dr. Jerusalem was routinely hired for such speaking arrangements by LTC sales representatives in other territories so he would continue his voluminous off-label prescribing of Zyprexa, often in sub-therapeutic doses designed to “snow” his patients.

142. Lilly’s routine practice of paying kickbacks to Dr. Jerusalem was intended to and did exacerbate his unethical off-label over utilization of Zyprexa for his patients.

143. Dr. Jerusalem and Lilly knew that the payments constituted kickbacks in reckless disregard of the law. They were also acutely aware that the safe harbors established by the HHS did not cover the exorbitant payments he was demanding. Defendant Jerusalem also knew that these payments were made for the express purpose of encouraging him to prescribe Zyprexa to his geriatric patients.

144. Dr. Jerusalem did not limit his illegal kickback agreements to Lilly. Rather, he also accepted lucrative payments from AstraZeneca. For example, the Plaintiff-Relator gained personal knowledge as a Lilly LTC sales representative that Dr. Jerusalem routinely made sweeping changes in his patient’s base medication patterns based upon kickbacks that he received from pharmaceutical companies. For example, Dr. Jerusalem began widely prescribing the atypical antipsychotic Seroquel, when AstraZeneca, Seroquel’s manufacturer, – appointed him to its “Advisory Board” to speak on behalf of Seroquel.

C. Dr. Jerusalem’s Retaliatory, Medically Unnecessary Wholesale Switching of Patient’s Antipsychotic Medications When His Kickback Demands are Refused by Eli Lilly

145. On or about October 2003, Dr. Jerusalem met with the Plaintiff-Relator and demanded that Plaintiff-Relator arrange for Lilly to hire his son, Jason Jerusalem, as a Lilly

sales representative. Dr. Jerusalem overtly threatened that if Lilly failed to employ his son, Dr. Jerusalem would immediately switch all of his patients to a competitor's antipsychotic.

146. Because of Dr. Jerusalem's importance to Zyprexa sales, Lilly afforded Jason Jerusalem every opportunity to succeed in Lilly's job application process. Plaintiff-Relator made sure that Lilly management hand-walked his resume through HR to make sure Jason Jerusalem received an interview. Plaintiff-Relator even provided hours of tutoring to Dr. Jerusalem's son in preparation for the interview.

147. Prior to the interview, Plaintiff-Relator met with Dr. Jerusalem at TGI Fridays, Dr. Jerusalem's favorite lunchtime restaurant. Dr. Jerusalem emphasized that it would be very embarrassing for him as a prominent medical professional if his son were to fail to get a job offer from Lilly.

148. Dr. Jerusalem specifically warned Plaintiff-Relator that "if you don't get my son a job it will be bad for you and Lilly" and even more to the point, "if my son he does not get a position with Lilly I will have to change what I am prescribing."

149. Despite Dr. Jerusalem's threats, Jason Jerusalem was not hired by Lilly. As he had threatened, Dr. Jerusalem retaliated by immediately starting to switch his thousands of patients from Zyprexa to a competing antipsychotic, AstraZeneca's Seroquel.

150. Dr. Jerusalem switching was done on such a wholesale basis that Plaintiff-Relator's Zyprexa sales plummeted by 33% among Dr. Jerusalem's patients in merely one month.

151. In order to justify the wholesale switches, Dr. Jerusalem falsified his billing for services that he was providing to indicate that he had treated the patients for whom he was switching medications because those patients were complaining of side effects from

Zyprexa and other ailments. In fact Dr. Jerusalem had not, and could not have, have provided such services to such a large number of patients over the course of one month.

152. Plaintiff-Relator gained personal knowledge of Dr. Jerusalem's retaliatory prescription switching through sales data provided to him by his employer. Plaintiff-Relator's sales performance was measured exclusively by drug sales revenues.

153. This abrupt switching was not based upon any medically reasonable basis such as the psychiatrist's concern over efficacy or safety or any side effects or adverse reactions of his patients; rather, his prescribing behavior was driven exclusively to punish Plaintiff-Relator, and Lilly, for failing to comply with his demand that his son be hired. As is detailed *infra*, Dr. Jerusalem's self-serving medical decision-making was to the medical detriment of his patients.

154. Thereafter, Plaintiff-Relator met with Dr. Jerusalem and his wife over lunch to discuss his dramatic drug switches. Plaintiff-Relator conveyed that numerous Directors of Nursing wanted to know why their patients stabilized on Zyprexa were so suddenly being switched to Seroquel. Plaintiff-Relator inquired what he was to tell the Directors of Nursing. Dr. Jerusalem glibly responded, "Do what you have to do."

155. The wholesale switches from Zyprexa to Seroquel in October 2003 is independently evidenced in patient records maintained by the LTC facilities at issue and reports generated by the LTC pharmacies, including the DURs described *supra*. Large scale, sudden swings in Dr. Jerusalem's patients' other prescriptions will also be documented by the patient records and DURs.

X. THE BAY PSYCHIATRIC DEFENDANTS' SUBMISSION OF FALSE CLAIMS FOR PSYCHIATRIC SERVICES THAT WERE NOT RENDERED AS STATED AND THE SUBMISSION OF FALSE RECORDS AND STATEMENTS TO GET CLAIMS PAID.

156. As alleged *supra*, in order to receive payment for services provided to Medicare and Medicaid beneficiaries, medical health care providers must sign and submit the standardized CMS-1500 form which carries express certifications that the CPT codes set forth in the form for which reimbursement is sought accurately reflect the nature and extent of services actually provided, and were medically necessary and that the information contained on the form is true and correct. 42 C.F.R. §424.32(b).

157. The Bay Psychiatric Defendants, in furtherance of their conspiracy, routinely signed and submitted claims with the knowledge that the claims contained materially false certifications.

158. Liability under the Government Plaintiff's False Claims Acts exists where (1) a healthcare provider knowingly submits a false claim seeking reimbursement from the Government for services that were never rendered and 2) a healthcare provider knowingly made or used a false record or statement to get a false or fraudulent claim paid by the Government. See *e.g.* §§3729(a)(1) and (2).

159. Each claim and/or record submitted by the Bay Psychiatric Defendants in violation of these provisions constitutes a violation of the Government Plaintiffs' False Claims Acts.

A. The Bay Psychiatric Defendants Knowingly False Billings Submitted to Medicare for Fictional Patient Visits.

160. Nursing homes are fertile grounds for billing fraud and abuse. Because nursing facilities house so many Medicare beneficiaries under one roof, unscrupulous billers of services can operate their schemes in volume. Dr. Jerusalem is one of those

unscrupulous practitioners who chose profits over the practice of medicine and has made a fraud-billing mill out of his substantial consulting psychiatric practice.

161. Dr. Jerusalem, by and through his alter ego Defendant Bay Psychiatric, acting in concert with his wife and office manager, Tesse Jerusalem, routinely submitted false or fraudulent claims to Medicaid and Medicare.

162. Psychiatric therapy sessions, like all services, must be performed and must be medically necessary in order to be eligible for reimbursement by Medicare.

163. Under Medicare, a doctor is not entitled to reimbursement for an office visit simply based upon the amount of time he spent with the patient; there must be some medically necessary service provided and there must be documentation of that service.

164. A large number of the psychiatric services that Dr. Jerusalem allegedly provided and for which his wife submitted claims were either not medically necessary or were unsupported by documentation.

165. The Bay Psychiatric Defendants also routinely over billed Medicare and Medicaid for psychotherapy sessions that had been provided.

166. For example, Dr. Jerusalem routinely spent 10 to 15 minutes or less with his patients, yet the bills prepared and submitted by Tesse Jerusalem the time of therapy to be 45 to 50 minutes.

167. Similarly, although Bay Psychiatric employed only one psychiatrist – Dr. Jerusalem - Bay Psychiatric billed for therapy sessions for an extraordinary number of patients in various facilities throughout the Florida panhandle each day, far more than it was physically possible for one person to see each day. The Bay Psychiatric Defendants' own records evidence that he was not providing the services claimed. Dr. Jerusalem's

records show him billing 18 to 20 hours a day, when he spent nowhere near that amount of time treating patients on a daily basis.

168. It was Dr. Jerusalem's routine pattern and practice to misrepresent therapy times and services ostensibly rendered to beneficiaries of the Medicare and Medicaid programs, and to instruct his wife to prepare false internal billing statements and records and claims for these false charges, and to submit such records and bills to the Medicare and Medicaid program, knowing that those claims were false.

169. Plaintiff-Relator gained personal knowledge of Dr. Jerusalem's fraudulent billing practices during communications with Dr. Jerusalem himself, as well as through first-hand communications with LTC DONs and nursing staff.

170. Plaintiff-Relator also saw Dr. Jerusalem's falsify written reports on several occasions.

171. Many DONs also reported in conversations with the Plaintiff-Relator that Dr. Jerusalem created false billing records for medication management services when he failed to provide such services. For example, Plaintiff-Relator discovered that a particular patient was visiting with family when Dr. Jerusalem reported evaluating the patient and ordered a medication switch.

172. Many Directors of Nursing at the facilities where Dr. Jerusalem served as the consulting psychiatrist also complained to Plaintiff-Relator that Dr. Jerusalem's documentation of patient therapy sessions contained falsified patient complaints, symptoms, or side effects that they had never seen the patients exhibit. One reason patients' symptoms were fabricated was to justify a switch from one atypical antipsychotic to another. Another reason was to create a paper record to justify billing

Medicare for a medication management session.

173. When Dr. Jerusalem provided “psychiatric services” to nursing home residents, he was required, pursuant to his consulting psychiatric agreements, to document his patient interaction. The documented information included the nature of the service provided, the time spent providing the service, the pharmacologic management or psychotherapy CPT codes, and any diagnosis-related information such as patient complaints and presenting symptoms. Dr. Jerusalem then was required to submit a copy of his patient records to the Director of Nursing of the facility.

174. The Directors of Nursing who reviewed Dr. Jerusalem patient records often became aware of Dr. Jerusalem’s falsification of patient records and communicated their concerns to Relator-Plaintiff. For example, the Directors of Nursing often complained to Relator-Plaintiff that Dr. Jerusalem’s documentation of patient interactions were contradicted by records prepared by the facility nursing staff.

175. Dr. Jerusalem and Tesse Jerusalem, through Bay Psychiatric Services, knowingly prepared false patient records on a regular basis with the intent to submit false claims for services. The Bay Psychiatric Defendants regularly submitted and were paid for false claims submitted to Medicare, Medicaid, and other government programs for services that had not been provided or for services for which the Bay Psychiatric Defendants had upcoded the claims.

B. Defendant Tesse Jerusalem’s Unlawful Conduct in Furtherance of the Bay Psychiatric Defendants’ Scheme to Defraud.

176. At all times relevant to the Complaint, Dr. Jerusalem vested responsibility for the day to day affairs of his alter ego Defendant Bay Psychiatric, including responsibility for preparing and submitting bills to Medicare and Medicaid, to his wife.

In this capacity, Tesse Jerusalem knowingly and willfully assisted her husband in preparing false claims and false documentation in support of Medicare claims that she ultimately submitted on behalf of Defendant Bay Psychiatric for psychological evaluations, group and individual therapy sessions, and medicinal management sessions, knowing these services had never been performed.

177. Among other things, Defendant Tesse Jerusalem manipulated claims forms by wording them to read as though Dr. Jerusalem had provided the patients with psychological evaluations and therapy, when in fact, he had not provided evaluation or therapy. She also prepared claims for psychiatric services with CPT codes chosen on the basis of maximum profit, not services actually rendered.

178. The claims prepared by Tesse Jerusalem contained the false certification that the claim complied with Medicare rules when compliance had in fact not occurred, as the services were not performed. These records were then presented to Medicare and other government programs as supporting documentation in an effort to obtain reimbursement for psychological services never provided to these patients.

179. Unaware of the Bay Psychiatric Defendants' unlawful agreement to deceive, Medicare and other government programs paid the myriad false claims.

180. Defendant Tesse Jerusalem's unlawful assistance of her husband's fraud enabled Dr. Jerusalem, by and through his alter ego Bay Psychiatric, to maximize the number of false claims submitted to and paid by Medicare and other government programs. This concerted action among the Bay Psychiatric Defendants constitutes an unlawful conspiracy to defraud the United States.

XI. DR. JERUSALEM'S UNLAWFUL CONDUCT ENDANGERED HIS PATIENTS' HEALTH AND SAFETY.

181. Nursing home neglect has been aptly called “the silent epidemic.” Many elderly and ill patients in assisted living facilities stifle their troubles for fear of revenge from those who are supposed to care for them, or, just as often they fail to recognize they are being neglected or abused.

182. Among the various examples of nursing home abuse is lack of appropriate supervision of patients' medication needs. This leads to inappropriate uses of drugs and serious treatment errors, which have resulted in physical danger to patients. It also can lead to the unnecessary physical or chemical restraint of patients.

183. The drugs of choice used to chemically restrain residents of long-term care facilities are atypical antipsychotic medications because of their known long-lasting sedative side effect.

184. Dr. Jerusalem's unethical abuse of atypical antipsychotics as a chemical restraint to pacify his patients for his convenience constitutes elder abuse. Numerous risks of harm, many with catastrophic consequences, are associated with the use of psychoactive drugs as chemical restraints. Toxic reactions to these drugs, especially in the elderly, are well documented in medical literature.

185. Examples of these adverse reactions include dizziness, tremors, uncontrolled muscle movements, excessive sedation, worsened mental functioning and confusion, increased agitation, respiratory depression, dehydration, constipation, and urinary incontinence.

186. Over sedation can also lead to loss of gag reflex, compromising the patient's ability to protect the airway. In addition, studies have shown psychoactive drug use among the elderly increases the risk of falls and hip fractures.

187. Dr. Jerusalem's use of atypical antipsychotics when his patients were not diagnosed with the narrow mental illnesses these drugs are indicated to treat was without medical necessity and was intended to chemically restrain.

188. 42 C.F.R. §483.13(a) provides that residents of skilled nursing facilities: "has[ve] the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms." *Id.*, see also 42 C.F.R. § 483.25(1)(1) (unnecessary medications).

189. Zyprexa is a dangerous drug even when prescribed for on-label use. It is even more dangerous for the elderly. On April 11, 2005, the FDA issued a public health advisory to alert health care providers, patients, and patient caregivers of its determination based upon clinical studies that using Zyprexa or the other atypicals to treat treating behavioral disorders in elderly patients with dementia is associated with increased mortality.

190. The FDA's examination of the specific causes of these deaths revealed that most were either due to heart related events (e.g., heart failure, sudden death) or infections (mostly pneumonia). Accordingly, the FDA required Lilly to amend Zyprexa's label to include a "black box warning" of this deadly side effect.

191. A 'black box' designation is an FDA-recommended/mandated warning based upon clinical research studies, for certain drugs that may cause serious and

potentially life-threatening side effects. The FDA requires that a black box warning be placed on the labeling or literature of a prescription drug, or in literature describing it. It is the strongest warning the FDA requires.

192. Six months later, on October 18, 2005, the Associated Press reported a study that showed atypicals used to treat elderly patients with dementia-related aggression and delusions can **raise their risk of death**. The researchers in the study pooled the results of 15 previous studies on atypicals Zyprexa, Risperdal, Seroquel and Abilify.

193. Among more than 5,000 elderly dementia patients, those taking any of the 4 drugs faced a **54% increased risk of dying within 12 weeks of starting the drugs**, compared to patients taking placebos. According to the AP article, there were 118 deaths among the 3,353 atypical users versus 40 in the 1,757 patients receiving a placebo and the risks were similar for each atypical.

194. Zyprexa is now known to cause a litany of other side effects across all age groups prescribed the drug, including the dramatically increased risk of obesity, diabetes type II, severe metabolic syndrome, hypertension, cardiovascular complications, heart attacks, and stroke. At the same time Zyprexa and other atypicals continue to cause neurological side effects like the older typical antipsychotics.

195. Dr. Jerusalem compounded the harm to his patients by engaging in dangerous wholesale switching of his patients' medications when financial incentives, not medical necessity, drove him to pick a new atypical of choice.

196. Medications within a therapeutic class are not interchangeable cogs. Each has its strengths and weaknesses depending on the patient's condition, other conditions the

patient may have, and the other medications a patient is taking. These medications also have different concentrations and levels of effectiveness.

197. Drug switching based on undisclosed financial reasons, when there is no valid medical reason to do so, is dangerous and medically unethical. The efficacy and safety of the prescription drug system relies upon the honesty and proper motivation of physicians to benefit patients in addition to the understanding that consumers, as laymen, typically do not know enough about the chemical make-up of powerful, FDA-regulated prescription drugs to evaluate the safety and efficacy of the medication treatments chosen for them by a medical professional.

198. The danger inherent in drug switching is exacerbated when the patients are elderly. The elderly are fragile and acutely susceptible to side effects, in addition to the fact that drugs are being prescribed off-label in a patient population at increased risk of stroke and death from the administration of such medications.

199. Because of the imprecision inherent in wholesale switching, the American Medical Association (“AMA”) has specifically condemned this practice. In their adopted Policies, the AMA opposes kickbacks-for-switches, denouncing the practice of recommending medication switches based on incentive payments.

200. The AMA also disfavors switching therapeutic alternatives in patients with chronic disease (such as hypertension, high cholesterol, etc.) who are stabilized on a drug therapy regime. (AMA Policy H-125.911 “Drug Formularies and Therapeutic Interchange.”)

201. The AMA’s concerns are not theoretical. They affected the thousands of patients of Dr. Jerusalem on a daily basis. This creates two great risks. First, as the AMA

noted, switching a patient from one medication to another when the patient is stabilized on the first medication, absent a clear medical indication that a switch is warranted, puts patients at risk. Second, because of the unique nature of each different medication within a particular therapeutic class, for any given patient Dr. Jerusalem's "atypical of choice" was often not the drug of choice from a medical standpoint.

202. Dr. Jerusalem's financially-driven dangerous across-the-board switching occurred without regard to the patients' individual needs and response to the prior antipsychotic. It is medically inappropriate, however, to switch antipsychotic therapy if the patient has had a productive response to the presently prescribed antipsychotic. Switching such patients to a different medication can result in loss of control of the condition, hospitalization, and other adverse outcomes.

203. Switching antipsychotic medications is particularly dangerous because there is no medically-recognized method to suddenly interchange antipsychotic drugs, especially when the psychiatrist trained in the chemical make-up of prescription medication fails to monitor the impact of the switch on patients' health

204. Dr. Jerusalem exacerbated the risk of serious complications by failing to monitor the medical condition of the nursing home patients subjected to his self-interested switching scheme.

205. Dr. Jerusalem purposefully generated a doctor-patient relationship with literally thousands of patients – far too many patients for him to monitor capably - when initiating one of his wholesale switching campaigns. Thus, once a switch was effectuated, Dr. Jerusalem was too busy effectuating medication switches at other facilities in the panhandle region.

206. Numerous Directors of Nursing raised concerns to Relator-Plaintiff about Dr. Jerusalem's neglect of vulnerable elderly patients, who were unable to arrange independently for psychiatric services.

207. Additionally, elderly residents of nursing facilities often take many medications simultaneously. Multiple medications not only add to the cost and complexity of therapeutic regimens, but also place patients at greater risk for adverse drug reactions and drug-drug interactions. Therefore, successful pharmacologic treatment in patients in this age-group can be difficult even if a responsible physician appropriately monitors his patients and their reactions to the interplay among their numerous medications.

208. Even when the switch did not cause any measurable medical impact on patients, Dr. Jerusalem's scheme resulted in such patients being prescribed extremely expensive medications that were unnecessary. The use of such medications to chemically restrain demanding patients is an improper justification for such a practice.

209. The well-pleaded facts establish that kickbacks, in cash and in kind, was the primary, if not sole, motive for Dr. Jerusalem's prescribing Zyprexa and other atypical antipsychotics. Were Dr. Jerusalem's motives pure, Dr. Jerusalem would not have routinely bragged about Plaintiff-Relator's outstanding sales numbers. It is also telling that Dr. Jerusalem chose to prescribe the risky atypical antipsychotics for sedation and sleep as opposed to medications within several classes of therapeutic drug classes that are FDA-approved for that use.

210. Among the available alternatives are medications within the 'hypnotics' therapeutic drug class on the market, or, medications chemically designed to induce a full night's sleep such as Lunesta and Ambien. Such drugs are not only far cheaper than the

expensive atypical antipsychotics, but also do not pose the significant risk of death to the elderly population.

211. Defendants' kickback scheme succeeded in exponentially increasing Dr. Jerusalem's personal profit, while at the same time generating huge consumption of Lilly's Zyprexa and other unnecessary drugs by geriatric patients who rely upon government healthcare programs to pay for their medical and prescription health benefits.

212. Dr. Jerusalem embarked upon this course of unlawful conduct with the knowledge that it would lead to the submission of a myriad of claims for Zyprexa, Seroquel, Risperdal, and other atypical antipsychotics and other medications by Medicare and Medicaid-participating pharmaceutical providers, when by law these claims were not reimbursable and would not have been reimbursed by the Medicaid and Medicare programs if the Plaintiff Governments had known the truth about Dr. Jerusalem's illegal, unscrupulous prescribing and billing schemes.

213. Defendants' conduct has unlawfully induced, *inter alia*, Medicaid to improperly pay hundreds of millions of dollars for ineligible claims for antipsychotics prescribed off-label each year. Compounding the financial impact of the profound rise in the number of claims for antipsychotics improperly caused by Dr. Jerusalem to be presented to the Government Plaintiffs for payment, antipsychotic unit monthly costs are hundreds of dollars more per prescription than the litany of sleep medications that are FDA-approved for the uses Dr. Jerusalem was prescribing antipsychotics.

XII. FINANCIAL HARM TO THE GOVERNMENT PLAINTIFFS

A. False Claims Caused to be Submitted for Ineligible Prescription Drugs.

214. Defendants' conspiracy and acts in furtherance thereof, as alleged *infra*,

has caused substantial financial harm to the Government Plaintiffs.

215. Specifically, the number of patients under Dr. Jerusalem's care at the time relevant to the Complaint ranged from 3000 to a peak of 5000, pursuant to his consulting psychiatrist agreements with the 150 nursing homes in the vast Florida Panhandle region. Conservatively, 20% of Dr. Jerusalem's patients – none of whom were diagnosed with an illness for which atypical antipsychotics are FDA-approved - were chemically restrained with Zyprexa.

216. Assuming *arguendo*, Dr. Jerusalem's total number of patients was only 3000, at a minimum 600 of Dr. Jerusalem's Medicare and Medicaid beneficiary patients were being prescribed Zyprexa off-label in exchange for kickbacks. According to Plaintiff-Relator, in 2003, a monthly regimen (30 pills) of Zyprexa's lowest pill dosage of 2.5 milligrams cost approximately \$200. Thus, the monthly cost to Medicaid for Dr. Jerusalem's unlawful kickback scheme with Lilly would have been \$120,000. Even under these extremely modest figures, Defendants' scheme caused false payments of at least \$1.4 million per year for ineligible Zyprexa claims.

217. The actual damages are believed to be much higher, because Dr. Jerusalem prescribed higher dosages of Zyprexa to some of his patients and Plaintiff-Relator believes the actual percentage of patients on Zyprexa was much higher. Plaintiff-Relator has personal knowledge that Dr. Jerusalem's kickback scheme with Lilly occurred over the course of approximately 3 years – from 2001 through October 2003.

218. The thousands of claims the Government paid to fund these Zyprexa purchases would not have been paid, but for Defendants' unlawful kickback joint venture. Each false claim for Zyprexa the Defendants caused to be submitted to the

Government pursuant to their illegal conspiracy is redressable under the civil and treble damages provisions of the Government-Plaintiffs' False Claims Acts. Without the benefit of discovery; however, Plaintiff-Relator is unable to accurately allege the total damages suffered by the Government Plaintiffs as a direct and proximate result of the Bay Psychiatric Defendants' fraudulent claims submissions.

219. The vast expenditures by state Medicaid programs evidence the astronomical damages caused by Lilly's unlawful promotion of Zyprexa. State Medicaid agencies purchased approximately 70% of the Zyprexa purchased in the United States in 2003.

220. For example, West Virginia's Department of Health and Human Services has paid at least \$70 million for Zyprexa in its Medicaid program since 1996. Similarly, California's Medicaid program known as Medi-Cal paid an extraordinary \$248.9 million for its beneficiaries' Zyprexa prescriptions in just a one-year period – from July 1, 2004 to June 30, 2005. The State of New York's Medicaid program expended \$205 million for Zyprexa in just the first 10 months of 2003.

B. Claims the Bay Psychiatric Defendants Submitted for Ineligible Prescription Drugs.

221. The knowingly false claims the Bay Psychiatric Defendants submitted directly to the Government Plaintiffs for psychiatric services, as alleged *infra*, are also redressable under the civil and treble damages provisions of the Government-Plaintiffs' False Claims Acts.

222. Plaintiff-Relator, based upon his employment and Lilly and first-hand admissions of Dr. Jerusalem, has personal knowledge that Dr. Jerusalem engaged in this kickback for switches schemes with other atypical antipsychotic manufacturers including

AstraZeneca and Janssen both before and after he entered into the corrupt financial relationship with Lilly. The damages reaped by Dr. Jerusalem's unlawful conspiracies with other drug manufacturers would have caused similar economic damage from the resulting false claims.

223. Further, elderly people have very specific problems and needs. There is seldom just one chronic illness for an elderly person to cope with; instead there are many. These are often accompanied by incapacitating disabilities and there are numerous drugs required to deal with each health problem. Upon information and belief, the Government Plaintiffs have suffered additional substantial damages from false claims caused to be submitted by Dr. Jerusalem's kickback schemes involving drugs in other therapeutic drug classes that are commonly prescribed to the elderly that fight ailments common to nursing homes – infections, stomach issues, high cholesterol, acid reflux and depression.

XIII. THE GOVERNMENT PLAINTIFFS' FALSE CLAIMS ACTS

224. The False Claims Act, 31 U.S.C. §§ 3729 to 3733, provides, in pertinent part that a person is liable to the United States Government for a civil penalty of not less than \$ 5,000 and not more than \$11,000, plus 3 times the amount of damages which the Government sustains because that person, *inter alia*,:

(a) Liability for certain acts. Any person who--

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(b) Knowing and knowingly defined. For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information--

(1) has actual knowledge of the information;

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

225. The False Claims Act defines “knowing” or “knowingly” expansively; no proof of specific intent to defraud is required. 31 U.S.C. §§3729(b)(1)-(3).

226. To cover its share of Medicaid spending, the Plaintiff States, including the State of Florida, enacted their own False Claims Acts. For example, Florida’s False Claims Act mirrors the broad proscriptions of the Federal False Claims Act, including those set forth in §§3729 (a)(1), (2), and (3). It provides in pertinent part:

§ 68.081 Short title; purpose

(1) Sections 68.081-68.09' may be cited as the “Florida False Claims Act.”

(2) The purpose of the Florida False Claims Act is to deter persons from knowingly causing or assisting in causing state government to pay claims that are false, and to provide remedies for obtaining treble damages and civil penalties for state government when money is obtained from state government by reason of a false claim.

§ 68.082 False claims against the state; definitions; liability

Any person who:

(a) Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency; or,

(c) Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid;

is liable to the state for a civil penalty of not less than \$5,000 and not more than \$10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

Id.

227. Under § 68.082(1)(c) of Florida's False Claims Act, "knowingly" is defined as, with respect to information, that a person: 1) Has actual knowledge of the information; 2) Acts in deliberate ignorance of the truth or falsity of the information; or 3) Acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. *Id.*

228. In addition, a defendant need not submit a claim directly to the Government for reimbursement for liability under the Government Plaintiffs' False Claims Acts. Rather, the governing False Claim Acts apply to anyone who knowingly assists in causing the Government to pay claims grounded in fraud, without regard to whether that person directly submitted a claim to the Government.

XIV. DEFENDANTS' LIABILITY UNDER THE GOVERNMENT PLAINTIFFS' FALSE CLAIMS ACTS.

A. The FDA's Regulatory Power

229. The pharmaceutical industry is highly regulated by the Food and Drug Administration ("FDA"). Pursuant to the Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, the FDA determines which drugs may be promoted and sold in the United States and strictly regulates the content of consumer and physician based advertising, direct-to-physician product promotion, and drug labeling information used by

pharmaceutical companies in promoting and selling FDA approved prescription drugs.

230. As detailed below, Lilly materially violated the FDA's regulations and federal law governing off-label marketing and truthful labeling and promotion of prescription drugs. Lilly engaged in this profit-driven misconduct for the purpose of deceiving physicians with their false and fraudulent off-label marketing message to cause the submission of false claims for Zyprexa to the Government Plaintiffs.

1. The FDA's Regulation of Sales, Labeling and Promotional Activities of Drug Manufacturers.

231. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-397, pharmaceutical drugs cannot be marketed for sale in the United States unless the drug's manufacturer obtains approval of the drug from the Food and Drug Administration ("FDA").

232. A drug's FDA-approved uses and dosages are called the drug's "indication." A drug's indication is set forth in the drug's labeling. Under 21 C.F.R. § 202.1(k)(2), drug manufacturers' marketing and promotional materials related to the drug aimed at physicians, *i.e.*, all brochures, handouts, detail aids, slide shows or other such promotional materials, are also defined as "product labeling" and are stringently regulated as such. By law, representations made in any labeling material must be truthful, not misleading and represent a fair balance of the information presented. Any failure to fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. *See* 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

233. Pharmaceutical promotional materials and presentations lacking in fair balance or that are otherwise false or misleading, violate the Food Drug and Cosmetics

Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated hereunder. Such violations exist where promotional and marketing materials and presentations for an FDA approved drugs reference “off label” uses, described *infra*, of the drug for which it was not an approved indication by the FDA, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated or are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

234. Lilly materially violated these clear cut labeling and misbranding regulations to illegally increase sales of its blockbuster drug in the off-label elderly market by and through its marketing and promotional efforts of its LTC sales force in direct-to-physician marketing.

235. Since Lilly cannot submit claims directly to Medicaid and Medicare, it intentionally defrauded LTC physicians to prescribe Zyprexa by engaging in a nationwide materially misleading off-label Zyprexa marketing campaign for the intended and foreseeable effect of causing physicians and pharmacists to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs’ regulations.

236. Each such claim Lilly knowingly caused to be submitted under these false pretenses in derogation of the labeling and misbranding laws, and each false statement it made to cause claims to get claims for Zyprexa paid, constitutes a false claim for which Lilly accountable under the Government Plaintiffs’ False Claims Acts.

2. Federal Law Prohibits Drug Manufacturers from Engaging in Off-Label Marketing To Protect the Health and Safety of Patients.

237. A drug's FDA-approved uses and dosages are called the drug's "indication." "Off-label" prescribing of drugs occurs when a drug is used by a medical professional beyond the drug's indication. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or to treat a different patient population (*e.g.* treating a child with the drug when the drug is approved to treat adults).

238. Pursuant to the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), an off-label use of a drug can cease to be off-label only if the manufacturer conducts studies and submits a new drug application demonstrating to the satisfaction of the FDA that the product is safe and effective for the proposed new use or uses. 21 U.S.C. §360aaa(b) and (c).

239. Because of its inherent dangers, off-label marketing by pharmaceutical companies is closely regulated by the FDA and the law. These regulations protect patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an ostensibly independent, scientific governmental body, the FDA.

240. Under the Food and Drug laws, **(1)** a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose (notably, however, Lilly's creation of a 280 person LTC sales force directly evidences Lilly introduced Zyprexa into interstate commerce with the specific intent that it be used for off-label purposes, *i.e.*, to treat vague cross-over symptoms in the elderly, as pleaded with specificity herein), and **(2)** a manufacturer illegally "misbrands" a drug if the drug's labeling describes intended uses for the drug that have not been approved by the FDA.

21 U.S.C. §§ 331, 352.

241. Accordingly, drug manufacturers are prohibited from actively marketing or promoting a drug for any unapproved indication, as alleged *supra*.

242. Although physicians are not prohibited from prescribing an FDA-approved drug “off-label” based upon their fully informed, independent medical judgment, pharmaceutical promotional activities and marketing materials and presentations are false or misleading in violation the Food Drug and Cosmetics Act and regulations promulgated hereunder if they advertise “off label” uses of a drug, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated.

243. When pharmaceutical companies illegally encourage off-label uses for their drugs, the number of prescriptions rises, thereby causing Medicaid and other programs to pay out more for prescriptions that are not eligible for payment. Lilly intended for its “off-label” promotional campaign to improperly increase the submissions of off-label Zyprexa prescriptions, including such prescriptions reimbursed by the Medicare and Medicaid programs.

244. Absent Lilly’s unapproved, illegal off-label marketing, its false representations concerning those medications and its gifts to physicians, Zyprexa would not have been prescribed by physicians for off-label indications. As a consequence, the elderly patients who have been prescribed Zyprexa for off-label indications were subject to the influence of unlawful financial inducements provided by Lilly

245. Lilly’s off-label marketing programs have been extremely successful, leading to the submission of claims to the Medicare and Medicaid programs for

medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

246. Claims for prescriptions induced to be written and submitted by providers to the Government for reimbursement as a direct and foreseeable result of Lilly's illegal off-label marketing campaign has caused the Plaintiff United States and the Plaintiff States to suffer substantial economic harm. Indeed, the cost of a Zyprexa treatment regimen with Zyprexa is substantially higher than the available FDA approved medications that would have been prescribed but for Lilly's duplicitous conduct.

247. Lilly marketed Zyprexa for off-label uses in violation of the FCA and knowingly caused doctors and pharmacists to file false reimbursement requests in violation of the False Claims Act. Any claim submitted for a drug when the drug was prescribed for an off-label use not only violates Medicare payment rules but also files a fraudulent claim under the False Claims Act. 31 USC §3802.

248. Placing profits ahead of the law, Lilly relentlessly targeted elderly LTC facility residents with its dangerous and illegal "off-label" marketing, promotional and advertising campaign for Zyprexa, resulting in an extreme undue financial burden foisted upon the publicly financed health system. The Government Plaintiffs' false claims acts were promulgated to redress the considerable financial harm that directly flows from illegal off-label marketing practices.

B. Zyprexa Prescribed Off-label to LTC Residents Was Ineligible for Reimbursement by the Medicaid Program.

249. Prior to the enactment of the Medicare Part D program, Medicaid purchased an estimated 80-90% of atypical antipsychotic prescriptions. Of the top 30 drugs by total US revenue, Zyprexa is the most expensive. As detailed herein, the FDA defines off-label

use as indications, dosage, form, dose regimen, population or other use parameter not mentioned in the approved labeling

250. Because prescriptions for off-label uses generally are not eligible for reimbursement, under Medicaid and Medicare regulations, submission of a claim for reimbursement for a drug prescribed off-label constitutes a false claim for the purposes of the Government Plaintiffs' False Claims Acts. While it is a pharmacy, by virtue of the reimbursement system, which unwittingly submits the false prescription drug claim, the person or persons who knowingly cause(s) such a claim to be presented to the Government Plaintiffs is liable under the law. Here, the Bay Psychiatric Defendants and Lilly's FCA violations arise from its successful attempts to induce LTC pharmacies to unwittingly defraud the government.

251. Dr. Jerusalem and Lilly knew that medically unnecessary, off-label Zyprexa prescriptions were ineligible for Medicaid reimbursement and that its activities would, in fact, cause numerous ineligible prescriptions to be submitted to Medicaid and Medicare by the LTC pharmacies which arranged for pharmaceutical benefits to Dr. Jerusalem's patients.

252. The unwitting participation of the LTC pharmacies in the submission of false claims was not only foreseeable; it was an intended consequence of Defendants' scheme of fraud.

253. Absent Lilly's intentional, illegal off-label marketing in the LTC demographic, and its unlawful financial relationships with doctors such as Dr. Jerusalem, Zyprexa would not have been prescribed off-label. Lilly's off-label marketing programs have been extremely successful, leading to the submission of claims to the Medicare and

Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

254. Each Zyprexa claim submitted to the Government Plaintiffs for Zyprexa prescribed for an off-label use not only violates Medicare payment rules, but constitutes the submission of a fraudulent claim redressable by the False Claims Act, 31 USC §3802, and the Plaintiff States' analogous laws.

255. The remedial provisions of the Government Plaintiffs' False Claims Act must be invoked to redress the substantial economic harm to the Medicare and Medicaid programs resulting from claims for prescriptions induced to be written and submitted by pharmacy benefits providers to the Government for reimbursement as a direct and foreseeable result of Lilly's illegal off-label marketing campaign. Dr. Jerusalem is equally liable under the Government Plaintiffs False Claims Acts for his knowing and intentional participation in Lilly's fraudulent billing scheme

256. Defendants' wanton misconduct has been ongoing since at least 2001 and up to and including October 2003.

XV. DEFENDANTS' ANTI-KICKBACK STATUTE VIOLATIONS CAUSED FALSE CLAIMS TO BE SUBMITTED TO THE GOVERNMENT.

A. Defendants Materially and Willfully Violated the Anti-Kickback Statute.

257. The Medicare and Medicaid Fraud and Abuse Statute (Statute) was first enacted under the Social Security Act in 1977. The Statute imposes criminal penalties on whomever violates the Anti-Kickback Provision and states in relevant part,

whoever knowingly and willfully offers or pays remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person:

- (A) to refer an individual to a person for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- (B) to purchase or lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal Health care program.

42 U.S.C. § 1320a-7b(b)(2)(A) & (B).

258. By its terms, the Federal Medicare and Medicaid Anti-Kickback Statute prohibits certain conduct involving improper payments in connection with the delivery of goods or services, including prescription drugs, covered by Medicare, Medicaid and other federal health care programs.

259. Under the Anti-Kickback Statute, not only is it unlawful to offer to pay kickbacks to impact a physician's prescribing choices, but it is equally unlawful for a physician to solicit and/or receive any payment in return for arranging for the furnishing of any item or service, including prescription drugs, that may be paid in whole or in part by the Medicare or Medicaid programs, or other federally-funded health care programs. Illegal payments or solicitations of payments include those in cash or in kind, *i.e.*, goods, those made directly or indirectly, and those made overtly or covertly.

260. A violation of the AKS arises if *one purpose* of the payment was to induce future referrals even if the payment was also intended to compensate for professional services. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989).

260. Such illegal inducement relationships between drug companies and physicians endanger patients and harm the Government Plaintiffs because, as here, they encourage unnecessary treatments, jaundice the free exercise of medical judgment by providers, limit patient options and lead to higher federal and state payments for prescription drug benefits. The Anti-Kickback Statute was promulgated to thwart such dangerous practice of medicine.

261. The remuneration paid by Lilly and accepted by Dr. Jerusalem and his alter ego Bay Psychiatric fit squarely within the AKS's definition of illegal remuneration. As alleged herein, in violation of the AKS, Lilly paid, and Dr. Jerusalem accepted, unlawful remuneration, including cash payments thinly-veiled as "speaker fees," travel fees for him and his wife, expensive dinners and entertainment, chartered fishing trips for himself and his friends and other gratuities as *quid pro quo* for Dr. Jerusalem's volume prescription writing of Zyprexa to his elderly LTC patients, notwithstanding the prohibitions of offering, paying or receiving items of value in exchange for arranging the purchase of any good paid for in whole or in part by the federal government.

262. Lilly further violated the AKS by entering similar unlawful inducement relationships with other physicians nationwide.

263. Dr. Jerusalem further violated the AKS by entering into unlawful kickback relationships with manufacturers of other drugs he prescribed to his Medicaid-beneficiary patients, including AstraZeneca and Janssen.

264. Defendants' conduct alleged supra plainly demonstrates Defendants' AKS violations were committed with the requisite scienter.

265. Although "safe harbor" regulations exist to protect certain relatively

innocuous and even beneficial commercial arrangements, no such provision protects the kickbacks demanded by and paid to Defendants.

266. An AKS violation is a predicate act for false claims act liability. Indeed, pursuant to the Government Plaintiffs' payment regulations, payment of a claim by Medicaid *is conditioned upon* the claim and underlying transaction complying with such laws, regulations, and program instructions, including the Federal anti-kickback statute. Thus, any good or service provided to a Medicare or Medicaid beneficiary pursuant to an illegal kickback arrangement is *ineligible* for reimbursement.

267. Defendants were aware of this condition, and yet engaged in conduct alleged herein that caused submitted claims for Zyprexa prescribed pursuant to their kickback arrangement knowing the Government Plaintiffs would not have paid the claims had they known of the AKS violations.

268. The Defendants prevented the Government Plaintiffs from knowing of their AKS violations by concealing their agreement.

269. In addition, Medical health care providers must sign and submit a claims form to seek reimbursement for health care services rendered to Medicare and Medicaid beneficiaries. Most states provide reimbursement for Medicaid providers *via* an electronic or paper-based claims process. In most states, the Medicaid claim form the LTC pharmacy benefits provider submits on a regular basis for reimbursement for Zyprexa and other prescription drugs contains a mandatory certifications about the services rendered. Among the required certifications is that the provider has complied with all laws and regulations pertaining to Medicaid, including the AKS.

B. Defendants' Anti-Kickback Statute Violations Caused the Submission of False Claims Giving Rise to Violations for Each Such Claims Submitted Under the Government Plaintiffs' False Claim Acts.

270. The Anti-Kickback Statute works hand in glove with the False Claims Act. As a matter of law, violations of the AKS state a cause of action under the False Claims Act. Indeed, compliance with the AKS, as well as all other relevant laws and regulations, is a condition of payment by Medicaid for prescription drug claims. 42 U.S.C. §1320a-7b(b).

271. Thus, where conduct that violates the Anti-Kickback Act results in goods and services (here, prescription drugs) provided to Medicare and Medicaid beneficiaries, that good or service is *ineligible* for reimbursement under Medicare and Medicaid payment rules and federal law.

272. Thus, as a matter of law, prescription drugs and other products purchased in violation of the AKS are ineligible for Government reimbursement. By and through their undisclosed financial arrangement, Defendants defrauded LTC pharmacies into presenting reimbursement claims for Zyprexa to the Government Plaintiffs containing the false certification that the claim was submitted in compliance with the AKS and other applicable regulations.

273. The Government would deny a claim if it had knowledge that the medication purchase giving rise to the claim was the product of an illegal kickback arrangement.

274. The Defendants complicity in a scheme to generate unlawful supplemental revenue from the stream of kickbacks paid to the Bay Psychiatric Defendants in exchange for writing Zyprexa prescriptions gives rise to liability under the Federal and State False Claims Acts by:

- causing the submission of claims requesting reimbursements for drugs that were selected on the basis of

maximum profit, without any medical basis; and,

- causing the submission of claims that contained a false certification that they had been submitted in compliance with the law, knowing that the Government conditioned payment of these claims upon such certifications.

275. Dr. Jerusalem, acting in concert with Defendant Lilly, as well as Janssen, AstraZeneca (and upon information and belief other drug manufacturers), caused LTC pharmacies such as Omnicare to submit claims that were rendered ineligible for reimbursement by the Defendants' violations of the AKS as well as caused LTC pharmacies to explicitly falsely certify that they were acting in compliance with all applicable laws and regulations, including the AKS, for each and every claim the pharmacies submitted for Dr. Jerusalem's prescriptions for his patients. The LTC pharmacies certifications Defendants caused to be submitted to the Government; however, were false when made.

276. LTC pharmacies reasonably and justifiably relied upon the validity and medical appropriateness of the prescriptions written by Dr. Jerusalem.

277. However, unbeknownst to them, Dr. Jerusalem put his personal financial gain ahead of patient safety and the law, and engaged in conduct that he knew would result in ineligible claims routinely being submitted for reimbursement and routinely allowed by the Government Plaintiffs.

278. It also cannot be legitimately disputed that Dr. Jerusalem and Defendant Lilly acted with the requisite scienter.

279. Dr. Jerusalem's illegal scheme, rife with false statements and fraudulent conduct, had one intended purpose and result – increasing personal profit – and therefore

claims for “pet” drugs such as Zyprexa instead of cheaper alternatives were submitted for payment from the Government.

280. As a direct and proximate result of these material misrepresentations and omissions, Dr. Jerusalem wrote unnecessary prescriptions for antipsychotics and other drugs for the medically illegitimate purpose of chemically restraining his patients and in the process, placed thousands of elderly patients in danger from these potent medications.

281. The arrangement was mutually beneficial. Defendant Lilly got what it paid for – a huge boost in Zyprexa market share due to thousands of switches to, and/or fills and refills, of the dramatically more expensive drug, creating a ready pool of additional revenues the Lilly used to fund the kickbacks to Dr. Jerusalem.

282. The result of the Defendants’ scheme was a dramatic increase in the number of claims submitted to the Government Plaintiffs for the higher priced Zyprexa, which led to dramatically higher revenue for Defendants. Defendants’ increased revenues, and the correspondingly-increased cost to the Government healthcare programs, were the direct, intended, and foreseeable result of the unlawful kickbacks to Dr. Jerusalem to maximize the number of drugs he prescribed.

283. Dr. Jerusalem knew the acceptance of the kickbacks he demanded was unlawful, as evidenced by the fact that Dr. Jerusalem and Lilly schemed to disguise and conceal the kickbacks, for example, by funneling money to Dr. Jerusalem under the guise of payment for bogus speaking arrangement. This is conduct which is by its nature fraudulent and designed to deceive.

284. Defendants’ liability under §§ 3729(a)(1) and (a)(2) of the Federal False Claims Act, §§ 68.082(a) and (b) of the Florida False Claims Act and the analogous laws

of the remaining Plaintiff States arises from their overt and willful participation in causing the basis for false claims to be made through the establishment of an illegal and corrupt financial relationships.

285. The Defendants conduct is also punishable under the Government Plaintiffs' False Claims Act provisions which prohibit unlawful conspiracies to cause the submission of false claims.

286. Defendant Jerusalem, through the solicitation and acceptance of bribes, has conspired with Lilly to cause thousands of false claims to be submitted to the Government on a daily basis. The Government would not have paid for prescriptions written by Dr. Jerusalem for antipsychotics and other expensive medications had the Government known they were a byproduct of Lilly's illegal kickback payments. Dr. Jerusalem prevented the Government Plaintiffs from having this knowledge through Dr. Jerusalem's routinely false record keeping and Defendants' other duplicitous conduct. Accordingly, the Defendants are liable under §§ 3729(a)(3) of the Federal False Claims Act, under §§ 68.082(c) of the Florida False Claims Act and under the analogous provisions of the remaining Plaintiff States' analogous laws for entering into an unlawful conspiracy to defraud the Government.

Upon information and belief supported by information gained during his employment with Lilly, Dr. Jerusalem engaged in the same unlawful kickback schemes with other manufacturers of atypical antipsychotics, including Janssen and AstraZeneca.

XVI. DISCOVERY

287. This complaint has identified the false claims presented and false records and statements made or used by the Defendants in furtherance of their fraudulent

schemes and set forth the basic framework, procedures, and the nature of the Defendants' fraudulent conduct. Discovery will be necessary to identify each false claim, record, and statement, because:

(a) the false claims presented, and caused to be presented, and the false records and statements made, used, or caused to be made or used, by Defendants in furtherance of their schemes are numerous and were presented over an extended period of time;

(b) Lilly required Plaintiff-Relator to return all of its so-called "proprietary" sales materials such as detail pieces and training materials as well as his laptop computer, cell phone materials, and any other Lilly information in his possession that would have evidence Lilly's scheme alleged herein; and,

(c) documents evidencing many of the false claims, records and statements are peculiarly within the possession of Defendants.

288. While some documentary evidence of the false claims, records and statements are within the possession of third parties such as the Centers for Medicare and Medicaid Services (CMS), Plaintiff-Realtor is legally prohibited from obtaining such records. *See* 45 C.F.R. §5.67 (The Department of Health and Human Services will not disclose names and addresses of individual beneficiaries of its programs, or benefits such individuals receive; or claim files maintained by the Social Security Administration, the Public Health Service, and the CMS).

COUNT I

**False Claims Act, 31 U.S.C. §3729(a)(1)
Presenting False Claims and Causing False Claims
(Against All Defendants)**

289. Plaintiffs incorporate by reference all of the preceding paragraphs of this complaint as if fully set forth herein.

290. This Count is brought by Plaintiff-Relator Woodward in the name of the United States under the *qui tam* provisions of 31 U.S.C. §3730 for the Bay Psychiatric Defendants' and Defendant Lilly's violations of 31 U.S.C. §3729 (a)(1).

291. At all times relevant and material to this Complaint, the Defendants caused false claims for payment or approval that they knew to be ineligible for reimbursement, to be presented to officers and employees of the federal and state governments. As a result, the United States Government paid the false claims submitted for the Zyprexa drugs by Omnicare and other Medicaid LTC provider pharmacies, resulting in great financial loss to the federal governments.

292. By virtue of the above-described acts, among others, the Bay Psychiatric Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and possibly continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees, or agents of the United States, for Seroquel, Risperdal, and other drugs.

293. By virtue of the above-described acts, among others, the Bay Psychiatric Defendants knowingly presented false or fraudulent claims for psychiatric service that were never provided for payment or approval, and possibly continues to submitted false or fraudulent claims for same for payment or approval, directly or indirectly, to officers,

employees, or agents of the United States.

294. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and possibly continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees, or agents of the United States, for Zyprexa.

295. By virtue of the above-described acts, Defendants knowingly and intentionally conspired to, and caused false claims for payment to be submitted for prescription drugs from the implementation of their kickback scheme between 2001 and April 2003.

296. It was the intended and foreseeable effect of Lilly's and the Bay Psychiatric Defendants kickback schemes to cause LTC pharmacies such as Omnicare to submit these false claims.

297. The amounts of the false or fraudulent claims to the United States were material.

298. Plaintiff United States, being unaware of the falsity of the claims caused to be made by the Bay Psychiatric Defendants and Defendant Lilly as alleged herein, and in reliance on the accuracy thereof paid and may continue to pay for prescriptions of Zyprexa, Seroquel, Risperdal and other drugs.

299. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

300. By reason of the conduct described above, the government has been damaged in an amount that is believed to be in excess of \$1.4 million annually for claims

submitted for just Zyprexa in the Florida panhandle alone. As the Defendant Lilly's fraudulent practices extend throughout the company in states where government reimbursement rates make such fraud lucrative for the Defendant Lilly; and as the Bay Psychiatric Defendants engaged in fraudulent practices with other drug companies to induce the Government to pay for other prescription drugs such as Seroquel and Risperdal; the amount of total damages to the government is much greater, in an amount to be proven at trial.

301. The United States *ex rel.* Plaintiff-Relator is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each ineligible claim submitted to the United States for payment.

COUNT II
False Claims Act, 31 U.S.C. §3729(a)(2)
Presenting False Statements and Records
To Get False Claims Paid
(Against All Defendants)

302. Plaintiffs incorporate by reference all of the preceding paragraphs of this complaint as if fully set forth herein.

303. The False Claims Act has been repeatedly violated by Defendant Lilly and the Bay Psychiatric Defendants through the fact that their conduct, individually and collectively, knowingly resulted in claims being made under Medicaid that violated the Anti-Kickback Statute, and that such claims were submitted to the Government by LTC pharmacy benefits providers being certified as not having violated this and/or other federal statutes. The submission of these falsely certified claims was the intended and foreseeable result of the Defendants' conduct.

304. By virtue of the above-described acts, among others, the Bay Psychiatric

Defendants knowingly made or used false records or statements to get false or fraudulent claims for psychiatric services that were not performed paid or approved by the Government, and possibly continues to make and use false records or statements to get such false or fraudulent claims paid or approved, directly or indirectly, to officers, employees, or agents of the United States.

305. By virtue of the above-described acts, among others, the Bay Psychiatric Defendants knowingly caused to be made or used false records or statements to get false or fraudulent claims paid or approved by the Government, and possibly continues to cause false records or statements to be made or used to get false or fraudulent claims paid or approved, directly or indirectly, to officers, employees, or agents of the United States, for Risperdal, Seroquel and other drugs.

306. By virtue of the above-described acts, among others, Defendant knowingly caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the government, and possibly continues to make or use false records or statements to get false or fraudulent claims paid or approved, directly or indirectly, to officers, employees, or agents of the United States, for Zyprexa.

307. The amounts of the false or fraudulent claims to the United States were material.

308. Plaintiff United States, being unaware of the falsity of records or statements caused to be made by the Bay Psychiatric Defendants, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa, Risperdal, Seroquel and other drugs. All unlawful conduct described above may have continued after Plaintiff-Relator Woodward's termination with Lilly.

309. Plaintiff United States, being unaware of the falsity of records or statements caused to be made by Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for its blockbuster drug Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator Woodward's termination with Lilly.

310. By reason of the conduct described above, the government has been damaged in an amount that is believed to be in excess of \$1.4 million annually for claims submitted for Zyprexa in the Florida panhandle alone. As the Defendant Lilly's fraudulent practices extend throughout the company in states where government reimbursement rates make such fraud lucrative for the Defendant Lilly; and the Bay Psychiatric Defendants entered into unlawful financial arrangements with other drug companies and caused the submission of false claims for other drugs pursuant thereto; the amount of total damages to the government is much higher, in an amount to be proven at trial.

311. The United States *ex rel.* Plaintiff-Relator is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each ineligible claim submitted to the United States for payment.

COUNT III
False Claims Act, 31 U.S.C. §3729(a)(3)
Conspiracy to Cause False Claims, Records and Statements
(Against all Defendants)

312. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

313. By the foregoing acts and omissions, Defendant Lilly entered unlawful marketing conspiracies with healthcare providers to defraud the United States by causing

false and fraudulent claims to be paid and approved in violation of the False Claims Act, 31 U.S.C. §3729(a)(3).

314. By entering the illegal financial relationship detailed herein in violation of the Anti-Kickback Statute, Defendant Lilly and the Bay Psychiatric Defendants conspired to violate the Federal False Claims Act by defrauding the government by causing the submission of false claims for Zyprexa.

315. By effectuating similar illegal financial relationships with other drug companies, including AstraZeneca, Janssen and others, the Bay Psychiatric Defendants conspired with such companies to defraud the government by submitting false claims and causing the submission of false claims for Seroquel, Risperdal and other drugs.

316. By effectuating a similar illegal financial relationship with other healthcare providers throughout the nation, Defendant Lilly and health care providers conspired to defraud the government causing the submission of false claims for Zyprexa.

317. Defendant Lilly committed overt acts in furtherance of its conspiracies as alleged *supra*, including Defendant Lilly's payments of kickbacks.

318. The Bay Psychiatric Defendants committed overt acts in furtherance of its conspiracies as alleged *supra*, including their solicitation and acceptance of kickbacks from Lilly, AstraZeneca, Janssen and other drug companies and writing unnecessary, off-label prescriptions of Zyprexa, Seroquel, Risperdal and other drugs to generate kickback revenues from drug companies.

319. The false or fraudulent claims to the government were material.

320. Plaintiff United States, being unaware of the falsity of the claims and/or statements caused to be submitted by the conspirators, and in reliance on the accuracy

thereof, paid and may continue to pay for Zyprexa, Seroquel and other drugs. All unlawful conduct described above may have continued after Plaintiff-Relator's employment with Lilly was terminated.

321. By reason of the conduct described above, the government has been damaged in an amount that is believed to be in excess of \$1.4 million annually for claims submitted for just for Zyprexa in the Florida panhandle alone. As the Defendant Lilly's fraudulent practices extend throughout the company in states where government reimbursement rates make such fraud lucrative for the Defendant Lilly; and the Bay Psychiatric Defendants entered into unlawful conspiracies with other drug companies and caused the submission of false claims for other drugs pursuant thereto, the amount of total damages to the government is much greater, in an amount to be proven at trial.

322. The United States *ex rel.* Plaintiff-Relator is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of \$5,500 to \$11,000 for each ineligible claim submitted to the United States for payment.

COUNT IV
Florida False Claims Act
Fl. Stat. §§68.081-68.09
(Against All Defendants)

323. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Florida under the *qui tam* provisions of Florida False Claims Act, Fl. Stat. §§68.081-68.09.

324. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Florida, including Zyprexa.

325. By virtue of the above-described acts, among others, Defendant Lilly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Florida, for Zyprexa.

326. The amounts of the false or fraudulent claims to the State of Florida were material.

327. Plaintiff State of Florida, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Zyprexa.

328. Defendant Dr. Jerusalem, by and through his alter ego Bay Psychiatric Services, at all times relevant to this action has provided, and continues to provide, psychiatric services and has prescribed psychotropic drugs in the State of Florida.

329. By virtue of the above-described acts, among others, the Bay Psychiatric Defendants caused to be presented false or fraudulent claims for payment or approval, and may continue to cause to be submitted, false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Florida, for Zyprexa and other drugs as well as for psychiatric services the Bay Psychiatric Defendants did not provide.

330. The amounts of the false or fraudulent claims to the State of Florida caused by the Bay Psychiatric Defendants to be submitted were material.

331. Plaintiff State of Florida, being unaware of the falsity of the claims caused to be submitted by the Bay Psychiatric Defendants, and in reliance on the accuracy

thereof paid and may continue to pay for improperly prescribed prescription drugs and to pay for psychiatric services that were never provided.

COUNT V
Conspiracy to Submit False Claims in Violation of
The Florida False Claims Act
Fl. Stat. §68.082(2)(C)
(Against All Defendants)

332. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

333. Dr. Jerusalem, at all times relevant to this action, has provided, and continues to provide, psychiatric services and has prescribed psychotropic drugs in the State of Florida.

334. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Florida, including Zyprexa.

335. As is alleged herein, the Bay Psychiatric Defendants entered into an unlawful conspiracy with Defendant Lilly. Both parties entered into the conspiracy willfully and intentionally.

336. By entering the illegal kickback agreement detailed herein, Lilly and the Bay Psychiatric Defendants conspired to defraud the State of Florida by causing the submission of false claims for Zyprexa.

337. As a result of the claims for reimbursement Defendants caused to be submitted to Florida Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Florida regularly made payments to pharmacies for Zyprexa.

338. The amounts of the false or fraudulent claims to the State of Florida were

material.

339. Plaintiff State of Florida, being unaware of the falsity of the claims and/or statements caused to be made by the Defendants, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT VI
Illinois Whistleblower Reward and Protection Act
740 ILCS 175/1 et seq.
(Against Defendant Lilly)

340. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Illinois under the *qui tam* provisions of 740 ILCS 175/4 for Defendant Lilly's violation of 740 ILCS 175/3.

341. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Illinois, including Zyprexa.

342. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Illinois, for Zyprexa.

343. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

344. The amounts of the false or fraudulent claims to the State of Illinois were material.

345. Plaintiff State of Illinois, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Zyprexa.

COUNT VII

**California False Claims Act
Ca. Government Code §12650 *et seq.*
(Against Defendant Lilly)**

346. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of California under the *qui tam* provisions of the California False Claims Act, California Government Code §12651(a).

347. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including Zyprexa, in the State of California.

348. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of California, for Zyprexa.

349. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

350. The amounts of the false or fraudulent claims to the State of California were material.

351. Plaintiff State of California, being unaware of the falsity of the claims caused to be submitted by Defendant Lilly and in reliance on the accuracy thereof paid, and continues to pay, for improperly prescribed Zyprexa.

COUNT VIII
Delaware False Claims Act
Del. Stat. Tit. VI. §1201
(Against Defendant Lilly)

352. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Delaware under the *qui tam* provisions of the Delaware False Claims and Reporting Act, Delaware Statute Title VI, Section 1201.

353. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Delaware, including Zyprexa.

354. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Delaware, for Zyprexa.

355. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

356. The amounts of the false or fraudulent claims to the State of Delaware were material.

357. Plaintiff State of Delaware, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Zyprexa.

COUNT IX

**District of Columbia False Claims Act
D.C. Stat. §2-308.03 *et seq.*
(Against Defendant Lilly)**

358. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the District of Columbia under the *qui tam* provisions of D.C. Stat. §2-308.03 *et seq.*

359. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the District of Columbia, including Zyprexa.

360. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the District of Columbia, for Zyprexa.

361. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

362. The amounts of the false or fraudulent claims to the District of Columbia were material.

363. Plaintiff District of Columbia, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Zyprexa.

COUNT X

**Hawaii False Claims Act
Haw. Rev. Stat. §661-21 *et seq.*
(Against Defendant Lilly)**

364. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Hawaii under the *qui tam* provisions of Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*

365. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Hawaii, including Zyprexa.

366. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Hawaii, for Zyprexa.

367. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

368. The amounts of the false or fraudulent claims to the State of Hawaii were material.

369. Plaintiff State of Hawaii, being unaware of the falsity of the claims caused to be submitted by Defendant, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Zyprexa.

COUNT XI

**Louisiana Medical Assistance Programs Integrity Law
Louisiana Rev. Stat. §437 *et seq.*
(Against Defendant Lilly)**

370. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Louisiana under the *qui tam* provisions of the Louisiana Medical Assistance Programs Integrity Law, Louisiana Rev. Stat. §437 *et seq.*

371. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Louisiana, including Zyprexa.

372. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Louisiana, for Zyprexa.

373. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

374. The amounts of the false or fraudulent claims to the State of Louisiana were material.

375. Plaintiff State of Louisiana, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof paid and continues to pay for improperly prescribed Zyprexa.

COUNT XII

**Massachusetts False Claims Act
Massachusetts Gen. Laws c.12 §5(A)
(Against Defendant Lilly)**

376. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Massachusetts under the *qui tam* provisions of the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A).

377. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the Commonwealth of Massachusetts, including Zyprexa.

378. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the Commonwealth of Massachusetts, for Zyprexa.

379. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

380. The amounts of the false or fraudulent claims to the State of Massachusetts were material.

381. Plaintiff Commonwealth of Massachusetts, being unaware of the falsity of the claims caused to be submitted by the Defendant's conspiracies and in reliance on the accuracy thereof, paid and continues to pay for improperly prescribed Zyprexa.

COUNT XIII
Montana False Claims Act
2005 Mont. Code, CH. 465, HB 146, et seq.
(Against Defendant Lilly)

382. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Montana under the *qui tam* provisions of the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, *et seq.*

383. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including Zyprexa, in the State of Montana.

384. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and may continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Montana, for Zyprexa.

385. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

386. The amounts of the false or fraudulent claims Defendant Lilly caused to be made to the State of Montana were material.

387. Plaintiff State of Montana, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof, paid and may continue to pay for improperly prescribed Zyprexa.

388. At all times relevant to the complaint, Lilly acted with the requisite knowledge.

389. As a direct and proximate consequence of Defendant Lilly's conduct, the State of Montana has suffered significant, material financial damages in an amount to be proved at trial.

390. The State of Montana would not have suffered these devastating losses had the truth about Defendant's marketing conspiracies been known.

COUNT XIV
Tennessee Medicaid False Claims Act
Tenn. Stat. §§75-1-181 *et seq.*
(Against Defendant Lilly)

391. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Tennessee under the *qui tam* provisions of the Tennessee Medicaid False Claims Act, Tenn. Stat. §§75-1-181 *et seq.*

392. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Tennessee, including Zyprexa.

393. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Tennessee, for Zyprexa.

394. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

395. The amounts of the false or fraudulent claims to the State of Tennessee were material.

396. Plaintiff State of Tennessee, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Defendant's improperly prescribed drug Zyprexa.

COUNT XV

**Texas Medicaid Fraud Prevention Act
Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*
(Against Defendant Lilly)**

397. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Texas under the *qui tam* provisions of the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*

398. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Texas, including Zyprexa.

399. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Texas, for Zyprexa.

400. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

401. The amounts of the false or fraudulent claims to the State of Texas were material.

402. Plaintiff State of Texas, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof paid and continues to pay for Defendant's improperly prescribed drug, Zyprexa.

COUNT XVI

**Virginia Fraud Against Taxpayers Act
Va. Stat. Ch. 842, Article 19.1, § 8.01-216.1 *et seq.*
(Against Defendant Lilly)**

403. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the Commonwealth of Virginia under the *qui tam* provisions of the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, § 8.01-216.1 *et seq.*

404. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the Commonwealth of Virginia, including Zyprexa.

405. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be presented false or fraudulent claims for payment or approval, and may continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the Commonwealth of Virginia, for Zyprexa.

406. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

407. The amounts of the false or fraudulent claims to the Commonwealth of Virginia were material.

408. Plaintiff Commonwealth of Virginia, being unaware of the falsity of the claims caused to be submitted by the Defendant Lilly, and in reliance on the accuracy thereof paid and continues to pay for Defendant's improperly prescribed drug Zyprexa.

COUNT XVII
Indiana False Claims and Whistleblower Act
(IC 5-11-5.5 *et seq.*)
(Against Defendant Lilly)

409. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

410. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Indiana under the *qui tam* provisions of IC 5-11-5.5-4 for the Defendant Lilly's violations of IC 5-11-5.5-2.

411. Defendant Lilly, at all times relevant to this action, sold and continues to sell pharmaceuticals in the State of Indiana, including Zyprexa.

412. Through the acts described above and otherwise, Defendant Lilly knowingly caused to be presented for payment and approval to the Indiana Medicaid program, possibly continues to cause to be presented, directly or indirectly, to officers, employees or agents of the State of Indiana, false and fraudulent claims in order to induce Medicaid reimbursement for Zyprexa, and Defendant Lilly's other drugs, that were not eligible for any such reimbursement.

413. Through the acts described above and otherwise, Defendant Lilly knowingly caused to be made or used and continues to cause to be made or used, false and fraudulent statements and/or records, in order to induce Medicaid reimbursement for Zyprexa that were not eligible for any such reimbursement.

414. As a result, Plaintiff Indiana reimbursed Medicare and Medicaid participating providers for ineligible claims of Zyprexa, resulting in material financial losses to the State of Indiana.

415. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

416. Plaintiff State of Indiana, unaware of the falsity of the claims caused to be presented by Defendant Lilly, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Zyprexa that would not have been paid or approved in any part if the truth were known.

417. Plaintiff State of Indiana, unaware of the falsity of the records or statements caused to be made or used by Defendant Lilly, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Zyprexa that would not have been paid or approved in any part if the truth were known.

418. By reason of Defendant Lilly's wrongful conduct, Indiana has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the state's false claims act in an amount to be determined at trial, plus civil penalties for each such false statement caused to be made or used by Defendant Lilly.

COUNT XVIII
Nevada False Claims Act
Nevada Rev. Stat. §357.010 *et seq.*
Submission of False Claims to State or Local Government.
(Against Defendant Lilly)

419. Plaintiffs reallege and incorporate by reference each and every of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-

Relator Woodward in the name of the State of Nevada under the *qui tam* provisions of Nevada Rev. Stat. §357.010 *et seq.*, “Submission of False Claims to State or Local Government.”

420. Defendant Lilly, at all times relevant to this action, sold and continue to sell pharmaceuticals in the State of Nevada, including Zyprexa.

421. At all times relevant and material to this Complaint, Defendant Lilly knowingly caused false claims for payment or approval for Zyprexa to be presented to officers and employees of the federal and state governments. As a result, the federal and state governments reimbursed Medicaid provider pharmacies for ineligible claims for Zyprexa, resulting in great financial loss to the Nevada government.

423. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

424. By virtue of the above-described acts, among others, Defendant Lilly knowingly caused to be made or used and continues to cause to be made or used false or fraudulent statements to get claims allowed or paid for Zyprexa by the State of Nevada, for Zyprexa.

425. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

426. The amounts of the false or fraudulent claims and statements caused to be made by Lilly to the State of Nevada were material.

427. Plaintiff State of Nevada, being unaware of the falsity of the claims and/or statements caused to be made or used by Defendant Lilly, and in reliance on the accuracy thereof paid and continues to pay for Defendant’s improperly prescribed drug Zyprexa.

COUNT XIX

New Hampshire False Claims Act

(167:61-b *et. seq.*)

(Against Defendant Lilly)

428. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of New Hampshire under the *qui tam* provisions of New Hampshire False Claims Act, 167:61-b *et. seq.*

429. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of New Hampshire.

430. Through the acts described above and otherwise, Defendant Lilly knowingly caused to be presented for payment and approval to the New Hampshire Medicaid and Medicare programs, and continues to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of New Hampshire, to induce Medicaid and/or Medicare reimbursement for claims for Zyprexa that were not and are not eligible for any such reimbursement.

431. Through the acts described above and otherwise, Defendant Lilly knowingly caused to be made or used, and continues to cause to be made or used, false and fraudulent records and/or statements, in order to get claims for Zyprexa allowed or paid by Medicaid and/or Medicare, that were not eligible for any such reimbursement.

432. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

433. The amounts of the false or fraudulent claims to the State of New Hampshire were material.

434. Plaintiff State of New Hampshire, unaware of the falsity of the claims presented or caused to be presented by Defendant Lilly, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Defendant Lilly's Zyprexa that would not have been paid or approved in any part if the truth were known.

435. Plaintiff State of New Hampshire, unaware of the falsity of the records or statements caused to be made or used Defendant Lilly, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Defendant Lilly's Zyprexa that would not have been paid or approved in any part if the truth were known.

436. By reason of Defendant Lilly's wrongful conduct, New Hampshire has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum penalties for each such false statement caused to be made or used by Defendant Lilly and each such false claim caused to be submitted by Defendant Lilly.

COUNT XX

New Mexico

Medicaid False Claims Act

(740 ILCS 175/3)

(Against Defendant Lilly)

437. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of New Mexico under the *qui tam* provisions of the New Mexico Medicaid False Claims Act 740 ILCS 175/3 *et seq.*

438. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of New Mexico, including Zyprexa.

439. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

440. Through the acts described above and otherwise, Defendant Lilly knowingly caused to be presented for payment and approval to the New Mexico Medicaid and/or Medicare programs, and may continue to cause to be presented, false and fraudulent claims directly or indirectly, to officers, employees or agents of the State of New Mexico, in order to induce Medicaid and/or Medicare reimbursement for claims for Zyprexa that were not eligible for any such reimbursement.

441. Through the acts described above and otherwise, Defendant Lilly knowingly caused to be made or used, and may continue to cause to be made or used, false and fraudulent records and/or statements, in order to get claims for Zyprexa allowed or paid by Medicaid and Medicare that were not eligible for any such reimbursement.

442. The amounts of the false or fraudulent claims caused to be made to the State of New Mexico were material.

443. Plaintiff State of New Mexico, unaware of the falsity of the claims presented or caused to be presented by Defendant Lilly, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for Zyprexa that would not have been paid or approved in any part if the truth were known.

444. Plaintiff State of New Mexico, unaware of the falsity of the records or statements caused to be made or used by Defendant Lilly, and in reliance on the accuracy

thereof, have paid and approved, and may continue to pay and approve, claims for Defendant Lilly's Zyprexa that would not have been paid or approved in any part if the truth were known.

445. By reason of Defendant Lilly's wrongful conduct, New Mexico has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum civil penalty allowed under the state law for each such false claim caused to be submitted by Defendant Lilly and each such false statement caused to be made or used by Defendant Lilly.

COUNT XXI

**Michigan Medicaid False Claims Act
(M.C.L.A. 400.601 *et seq.*)
(Against Defendant Lilly)**

446. Plaintiffs incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Plaintiff-Relator Woodward in the name of the State of Michigan under the *qui tam* provisions of the Michigan False Claims Act, M.C.L.A. 4000.601 *et seq.*

447. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Michigan, including Zyprexa. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

448. Through the acts described above and otherwise, Defendant Lilly knowingly caused to be presented for payment and approval to the Michigan Medicaid and/or Medicare programs, and may continue to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of

Michigan, in order to induce Medicaid and or Medicare to reimburse Medicaid or Medicare participating pharmaceutical providers for purchases of Zyprexa for Medicaid beneficiaries when those claims were not and are not eligible for any such reimbursement.

449. Through the acts described above and otherwise, Defendant Lilly knowingly caused to be made or used, and may continue to cause to be used or made, false and fraudulent records and/or statements, in order to get claims for Zyprexa allowed or paid by Medicaid and/or Medicare that were not eligible for any such reimbursement.

450. The amounts of the false or fraudulent claims to the State of Michigan were material.

451. Plaintiff State of Michigan, unaware of the falsity of the claims caused to be presented by Defendant Lilly, and in reliance on the accuracy thereof, have paid and approved, and may continue to pay and approve, claims for Zyprexa that would not have been paid or approved in any part if the truth were known.

452. Plaintiff State of Michigan, unaware of the falsity of the records or statements caused to be made or used by Defendant Lilly, and in reliance on the accuracy thereof, have paid and approved, and may continue to pay and approve, claims for Zyprexa that would not have been paid or approved in any part if the truth were known.

453. By reason of Defendant Lilly's wrongful conduct, Michigan has suffered substantial financial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum allowable civil penalties for each such false statement caused to made or used by Defendant Lilly and each such false claim caused to be made by Defendant Lilly.

COUNT XXII
Conspiracy to Submit False Claims in Violation of
the Illinois Whistleblower Reward and Protection Act
740 ILCS 175/3(3)
(Against Defendant Lilly)

454. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

455. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of Illinois by causing the submission of false claims for Zyprexa. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

456. As a result of the claims for reimbursement Lilly caused to be submitted to Illinois Medicaid pursuant to their unlawful conspiracy, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Illinois regularly made payments to pharmacies for Zyprexa.

457. The amounts of the false or fraudulent claims to the State of Illinois were material.

458. Plaintiff State of Illinois, being unaware of the falsity of the claims and/or statements made by the conspirators, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXIII
Conspiracy to Submit False Claims in Violation of
the California False Claims Act
Ca. Gov't Code §12651(a)(3)
(Against Defendant Lilly)

459. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

460. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of California causing the submission of false claims for Zyprexa. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

461. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to California Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, California regularly made payments to pharmacies for Zyprexa.

462. The amounts of the false or fraudulent claims to the State of California were material.

463. Plaintiff State of California, being unaware of the falsity of the claims and/or statements made by Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXIV
Conspiracy to Submit False Claims In Violation of
the Delaware False Claims Act
Del. Code Tit. VI. §1201(a)(3)
(Against Defendant Lilly)

464. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

465. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of Delaware by submitting

false claims and causing the submission of false claims for Zyprexa. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

466. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Delaware Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Delaware regularly made payments to pharmacies for Zyprexa.

467. The amounts of the false or fraudulent claims to the State of Delaware were material.

468. Plaintiff State of Delaware, being unaware of the falsity of the claims and/or statements made by Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXV
Conspiracy to Submit False Claims In Violation of
the District of Columbia False Claims Act
D.C. Code §2-308.14(3)
(Against Defendant Lilly)

469. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

470. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the District of Columbia by submitting false claims and causing the submission of false claims for Zyprexa. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

471. As a result of the claims for reimbursement Defendant Lilly caused to be

submitted to District of Columbia Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, District of Columbia regularly made payments to pharmacies for Zyprexa.

472. The amounts of the false or fraudulent claims to the District of Columbia were material.

473. Plaintiff District of Columbia, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXVI
Conspiracy to Submit False Claims in Violation of
the Hawaii False Claims Act
Haw. Rev. Stat. §661-21(C)
(Against Defendant Lilly)

474. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

475. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of Hawaii by submitting false claims and causing the submission of false claims for Zyprexa.

476. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

477. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Hawaii Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit

providers, Hawaii regularly made payments to pharmacies for Zyprexa.

478. The amounts of the false or fraudulent claims to the State of Hawaii were material.

479. Plaintiff State of Hawaii, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXVII
Conspiracy to Submit False Claims in Violation of
the Indiana False Claims and Whistleblower Act
Ind. Code §5-11-5.5-2(b)(7)
(Against Defendant Lilly)

480. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

481. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of Indiana by submitting false claims and causing the submission of false claims for Zyprexa.

482. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

483. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Indiana Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment by pharmacy benefit providers, Indiana regularly made payments to pharmacies for Zyprexa.

484. The amounts of the false or fraudulent claims to the State of Indiana were material.

485. Plaintiff State of Indiana, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXVIII
Conspiracy to Submit False Claims in Violation of
the Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §438.3C
(Against Defendant Lilly)

486. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

487. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of Louisiana by submitting false claims and causing the submission of false claims for Zyprexa.

488. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

489. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Louisiana Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Louisiana regularly made payments to pharmacies for Zyprexa.

490. The amounts of the false or fraudulent claims to the State of Louisiana were material.

491. Plaintiff State of Louisiana, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct

described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXIX
Conspiracy to Submit False Claims in Violation of
the Massachusetts False Claims Act
Mass. Gen. Laws ch. 12 §5(B)(3)
(Against Defendant Lilly)

492. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

493. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the Commonwealth of Massachusetts by submitting false claims and causing the submission of false claims for Zyprexa.

494. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Massachusetts Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Massachusetts regularly made payments to pharmacies for Zyprexa.

495. The amounts of the false or fraudulent claims to the Commonwealth of Massachusetts were material.

496. Plaintiff Commonwealth of Massachusetts, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXX
**Conspiracy to Submit False Claims in Violation of
the Michigan Medicaid False Claims Act
Mich. Comp. Laws §400.606
(Against Defendant Lilly)**

497. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

498. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of Michigan by submitting false claims and causing the submission of false claims for Zyprexa.

499. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Michigan Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Michigan regularly made payments to pharmacies for Zyprexa.

500. The amounts of the false or fraudulent claims to the State of Michigan were material.

501. Plaintiff State of Michigan, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXXI
**Conspiracy to Submit False Claims in Violation of
the Nevada False Claims Act
Nev. Rev. Stat. §357.040(C)
(Against Defendant Lilly)**

502. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

503. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of Nevada by submitting false claims and causing the submission of false claims for Zyprexa.

504. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Nevada Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Nevada regularly made payments to pharmacies for Zyprexa.

505. The amounts of the false or fraudulent claims to the State of Nevada were material.

506. Plaintiff State of Nevada, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXXII

Conspiracy to Submit False Claims in Violation of the New Hampshire Medicaid Fraud and False Claims Act

N.H. Rev. Stat. §167:61-b (1)(c).

(Against Defendant Lilly)

507. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

508. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of New Hampshire by submitting false claims and causing the submission of false claims for Zyprexa.

509. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to New Hampshire Medicaid, which were falsely certified compliant with

federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, New Hampshire regularly made payments to pharmacies for Zyprexa.

510. The amounts of the false or fraudulent claims to the State of New Hampshire were material.

511. Plaintiff State of New Hampshire, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXXIII

**Conspiracy to Submit False Claims in Violation of
the New Mexico Medicaid False Claims Act**

**N.M. Stat. §27-14-4D
(Against Defendant Lilly)**

512. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

513. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers conspired to defraud the State of New Mexico by submitting false claims and causing the submission of false claims for Zyprexa.

514. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to New Mexico Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, New Mexico regularly made payments to pharmacies for Zyprexa.

515. The amounts of the false or fraudulent claims to the State of New Mexico were material.

516. Plaintiff State of New Mexico, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof, paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXXIV
Conspiracy to Submit False Claims in Violation of
the Tennessee Medicaid False Claims Act
Tenn. Stat. §71-5-182(C)
(Against Defendant Lilly)

517. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

518. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of Tennessee by submitting false claims and causing the submission of false claims for Zyprexa.

519. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Tennessee Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Tennessee regularly made payments to pharmacies for Zyprexa.

520. The amounts of the false or fraudulent claims to the State of Tennessee were material.

521. Plaintiff State of Tennessee, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXXV
Conspiracy to Submit False Claims in Violation of
the Texas Medicaid False Claims Act
Tx. Hum. Res. Code §36.002(9)
(Against Defendant Lilly)

522. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

523. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of Texas by submitting false claims and causing the submission of false claims for Zyprexa.

524. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Texas Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Texas regularly made payments to pharmacies for Zyprexa.

525. The amounts of the false or fraudulent claims to the State of Texas were material.

526. Plaintiff State of Texas, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXXVI
Conspiracy to Submit False Claims in Violation of
the Virginia Fraud Against Taxpayers Act
Va. Code §8.01-216.3(3)
(Against Defendant Lilly)

527. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

528. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the Commonwealth of Virginia by submitting false claims and causing the submission of false claims for Zyprexa.

529. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Virginia Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Virginia regularly made payments to pharmacies for Zyprexa.

530. The amounts of the false or fraudulent claims to the Commonwealth of Virginia were material.

531. Plaintiff State of Virginia, being unaware of the falsity of the claims and/or statements caused to be made by the Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

COUNT XXXVII
Conspiracy to Submit False Claims in Violation of
The Florida False Claims Act
Fl. Stat. §68.082(2)(C)
(Against the Bay Psychiatric Defendants)

532. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

533. Dr. Jerusalem, at all times relevant to this action, has provided, and continues to provide, psychiatric services and has prescribed psychotropic drugs in the State of Florida.

534. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals in the State of Florida, including Zyprexa.

535. As is alleged herein, the Bay Psychiatric Defendants entered into unlawful conspiracies with various drug companies, including AstraZeneca, Janssen and others, to promote the sale of their prescription drugs to Florida Medicaid beneficiaries. Dr. Jerusalem and the drug companies entered into the conspiracies willfully and intentionally.

536. By entering into illegal kickback agreements with drug companies, including AstraZeneca and Janssen as detailed herein, the Bay Psychiatric Defendants conspired to defraud the State of Florida by causing the submission of false claims for Zyprexa in exchange for the payment of lucrative kickbacks.

537. As a result of the claims for reimbursement the Bay Psychiatric Defendants caused to be submitted to Florida Medicaid, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, Florida regularly made payments to pharmacies for Seroquel, Risperdal and other drugs.

538. The amounts of the false or fraudulent claims to the State of Florida were material.

539. Plaintiff State of Florida, being unaware of the falsity of the claims and/or statements caused to be made by the Bay Psychiatric Defendants' conspiracies, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator's termination with Lilly.

JURY DEMAND

540. Plaintiffs demand trial by jury on all claims.

WHEREFORE, Relator-Plaintiff, on behalf of himself, the United States government and the Plaintiff States, requests the following relief:

(a) Judgment against Defendants, individually and jointly, in the amount of three (3) times the amount of damages the United States of America has sustained because of Defendants' actions, plus a civil penalty of \$11,000.00 for each action in violation of 31 U.S.C. § 3729, and the appropriate fines and penalties for violating the protective federal laws applicable to the fraudulent and false conduct and the cost of this action with interest;

(b) That this Court enter judgment against Defendant Lilly for the maximum amount of damages sustained by each State or District because of the Defendant Lilly's actions, plus the maximum civil penalty for each violation of the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, the California False Claims Act, Cal. Gov. Code §12651(a), the Delaware False Claims and Reporting Act, Del. Stat. Tit. VI. §1201, the District of Columbia False Claims Act, D.C. Stat. §2-308.03 *et seq.*, the Florida False Claims Act, Fl. Stat. §§68.081-68.09, the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*, the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §439, Massachusetts False Claims Act, Mass. Gen. Laws c.12 §5(A), the Michigan Medicaid False Claims Act, M.C.L.A. 400.601 *et seq.*, the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, *et seq.*, the Nevada False Claims Act, Nevada Rev. Stat. §357.010 *et seq.*, the New Hampshire False Claims Act, 167:61-b *et seq.*, the New Mexico False Claims Act, 740 ILCS 175/3, the Tennessee Medicaid False Claims Act,

Tenn. Stat. §§75-1-181 et seq., the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 et seq., Indiana False Claims and Whistleblower Act, IC 5-11-5.5 et seq. and the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, §8.01-216.1 et seq., plus interest.

(c) That this Court enter judgment against the Bay Psychiatric Defendants for the maximum amount of damages sustained by the State of Florida because of the Bay Psychiatric Defendants' conduct, plus the maximum civil penalty for each violation of the Florida False Claims Act, Fl. Stat. §§68.081-68.09.

(d) That Plaintiff-Relator be awarded the maximum amount allowed pursuant to Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, the California False Claims Act, Cal. Gov. Code §12651(a), the Delaware False Claims and Reporting Act, Del. Stat. Tit. VI. §1201, the District of Columbia False Claims Act, D.C. Stat. §2-308.03 *et seq.*, the Florida False Claims Act, Fl. Stat. §§68.081-68.09, the Hawaii False Claims Act, Haw. Rev. Stat. §661-21 et seq., the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §439, Massachusetts False Claims Act, Mass. Gen. Laws c.12 §5(A), the Michigan Medicaid False Claims Act, M.C.L.A. 400.601 et seq., the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, et seq., the Nevada False Claims Act, Nevada Rev. Stat. §357.010 et seq., the New Hampshire False Claims Act, 167:61-b et seq., the New Mexico False Claims Act, 740 ILCS 175/3et seq., the Tennessee Medicaid False Claims Act, Tenn. Stat. §§75-1-181 et seq., the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 et seq., Indiana False Claims and Whistleblower Act, IC 5-11-5.5 et seq. and the Virginia Fraud

Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, §8.01-216.1 et seq., plus interest, and all relief to which they are entitled pursuant to said laws


(e) That the Relator-Plaintiff be awarded all costs incurred, including reasonable attorneys' fees;

(f) In the event that the United States or any one or all of the Plaintiff States proceed with this action, Plaintiff-Relator Woodward, be awarded an appropriate amount for disclosing evidence or information that the United States and/or the Plaintiff States did not possess when this action was brought to the government. The appropriate amount is not greater than twenty-five percent (25%) of the proceeds of the action or settlement of a claim. The amount awarded to Plaintiff-Relator also includes the results of government actions or settlement of claims resulting from the expansion of claims through the government's further investigation directly generated from or attributable to Plaintiff-Relator's information; and,

(g) Such other relief as this Court deems just and appropriate.

Respectfully submitted,

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